The 510(k) Process:  
The Key to Effective Device Regulation

AdvaMed  
Advanced Medical Technology Association
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1.0 Executive Summary

The Medical Device Amendments of 1976 ensure that medical devices are appropriately regulated by creating a risk-based and science-driven classification system. Through continual process improvements, today’s regulatory scheme, including the premarket notification (“510(k)”) process, is a very successful and effective means by which to ensure the safety and effectiveness of medical technology while encouraging device development and facilitating the availability of high quality medical devices to meet the needs of the American public.

The United States (“US”) Food and Drug Administration’s (“FDA” or “Agency”) 510(k) process for medical devices is of critical importance in ensuring that medical devices are neither under-regulated nor over-regulated. Contrary to misconceptions, the 510(k) program is not simply a means to allow devices onto the market that are equivalent to “grandfathered” devices of the past. It is a highly flexible and efficient means to appropriately regulate today’s diverse medical technology, and is only one part of a larger regulatory framework designed to ensure the continuing safety and effectiveness of medical devices. Based on the history of the program, it is reasonable to expect that the 510(k) process will continue to evolve to provide public health protection without stifling innovation.

This critical regulatory program is too often misunderstood and mischaracterized, but has tremendous significance in the everyday lives of our citizens. Unknown to most Americans, FDA regulation of medical devices encompasses a wide range of products, from simple tongue depressors to complex artificial hearts. Although largely unrecognized, it is estimated that 90% of medical devices have been authorized to be marketed in the US through the 510(k) process. The lack of appreciation for the contributions of the 510(k) program to public health protection draws unfair criticism of FDA and the program.

The 510(k) process is a durable program that has withstood the test of time, and is a reasonable means for applying the appropriate degree of regulation of medical devices in the US. Although Congress has revisited the regulation of medical devices on several occasions over the years, increasing FDA’s authority and refining regulatory requirements, it has not altered this basic approach to ensuring the safety and effectiveness of medical devices. This paper describes the evolution of the unique framework for the FDA regulation of medical devices, with an emphasis on the 510(k) process, detailing the integrity and strengths of the 510(k) program, alleviating common confusion surrounding the program and supporting the continuation of the program into the foreseeable future.

1 Refers to Section 510(k) of the Federal Food, Drug, and Cosmetic Act
2.0 Introduction

FDA has been responsible for the regulation of medical devices and diagnostic products in the US for more than 30 years. This federal agency, established in the early 1900s to ensure the quality of foods and drugs entering domestic commerce, received broad authority from Congress in 1976 to review and monitor the manufacture and use of medical devices. This regulatory scheme is designed to ensure that medical devices are “safe and effective” before entering the US marketplace and is extremely stringent.

The Center for Devices and Radiological Health (“CDRH” or “Center”) is the organizational component within FDA responsible for these regulatory efforts, which encompass all aspects of product evaluation, manufacturing, and distribution.\(^2\) FDA’s CDRH regulates the clinical investigation and premarket review of new medical products, as well as their post-market performance. In addition, the Center establishes controls on manufacturing that are intended to assure product quality and integrity, and it possesses strong enforcement tools to assure compliance with regulatory standards and processes.

CDRH is responsible for regulating not only high-tech devices designed to prevent, diagnose, or treat the full range of health problems, but also more common products, like bandages, splints, and surgical drapes, that pose little risk. According to CDRH, more than 20,000 companies worldwide produce over 80,000 brands and models of medical devices in the US marketplace. The Center’s job is to ensure that all devices are safe and effective. In fiscal year 2005, CDRH cleared or approved over 2,813 new products for marketing, including 14 devices representing breakthrough technologies.\(^3\) In that same period, the Center approved 75 new clinical studies designed to test the safety and effectiveness of experimental medical devices in humans.

Given the breadth of products defined as medical devices, effective regulation is complicated. The key challenge facing CDRH as it regulates medical devices in the 21st century is the same one that confronted FDA in 1976, when the Agency was charged by Congress to regulate these products—balancing FDA’s mission of protecting the public health with that of advancing the public health through timely availability of new products.

Because of the heterogeneity of medical devices appropriate scientific evaluation methods vary for different devices and no one regulatory approach will sufficiently accommodate all devices. In practice, this challenge means that CDRH has to achieve a delicate balance in three primary areas:

\(^2\) CDRH resulted from the merger of the Bureau of Medical Devices and the Bureau of Radiological Health in mid-1982.

• Timely Product Review Processes—the need to review medical device products in a timely manner. The aim is to avoid undue delay in making new products available to patients and the physicians who often use them. Product review times serve as a barometer of how well the medical device Center is balancing its regulatory responsibilities.

• Appropriate Regulatory Requirements—the need to ensure that the regulatory burden that is imposed on product innovators is appropriate and reasonable. The challenge is to calibrate the level of regulation to the risk of the product, without stifling innovation. The diversity in devices complicates this task.

• Science-Based Reviews—the need to keep pace with scientific advances through efficient regulatory processes. The objective is to construct sound science-based regulatory processes that are current with today’s knowledge base, and to do this via the most efficient and effective means possible.

In the three decades since Congress gave FDA responsibility for medical device oversight, the regulatory framework set forth in the 1976 statute has become a state-of-the-art risk management tool and has proven itself to be remarkably valuable—because of its ability to accommodate the wide range of types of medical devices and the ways in which device innovation takes place.

While placing emphasis on the evolution of the 510(k) process, this document explains this unique and often misunderstood regulatory framework that encompasses virtually all medical devices and lays out the characteristics of medical device innovation that complicate the task of regulation. In addition, it addresses the major changes and refinements Congress and FDA have made in medical device regulation over the years as they pertain to the 510(k) process. Finally, it presents the reasons for the success of the 510(k) process and supports its continuation.

### 3.0 Medical Device Innovation

More than 8,000 new medical devices are marketed each year in the US. These devices vary widely and include everything from capital equipment to disposable and reusable instruments. They comprise technologies used for disease screening and diagnosis, as well as for therapeutic uses. They encompass low-cost commodity supplies and high-cost durable goods and equipment. They range from molecular diagnostics to implantable products to bandages. Table 1 lists the chief characteristics of the medical device industry.

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Table 1
Characteristics of the Medical Device Industry

| • Diversity in device types, complexity, and risk  
| • Rapidly evolving device design  
| • Short product life cycles  
| • Relatively small markets  
| • Multiple competitors  
| • High percentage of small companies |

Some medical devices are, in essence, new iterations or refinements of existing technology. Others represent new directions in medical care and can be considered “breakthrough” technologies. Sometimes, changes in existing medical technologies—due to new power sources, materials or components, or design—are so significant that they might be considered “breakthroughs” themselves, bringing about a generational change in the device. Other incremental changes in device design or features, purpose, or use, though quite small in themselves, often accumulate over time, transforming medical devices and improving their clinical effectiveness.

In addition to the wide variety of device types, medical devices vary in their complexity and in their degree of risk and benefit to the patient. Because of this heterogeneity, appropriate scientific evaluation methods also vary for different devices. This diversity of medical devices led policymakers, both in Congress and federal health agencies, to conclude that no one regulatory approach was appropriate for such a wide range of product types, and that devices required FDA regulatory pathways and effectiveness standards different from those that had already been established for new drugs.5

Other noteworthy characteristics of medical devices are their relatively short product life cycles, small markets, and the level of competition that exists in their markets (especially when compared to drugs). FDA’s leadership is aware of these drug/device differences, noting the short product life cycle of medical devices in an issue of the *New England Journal of Medicine*: “Although drugs are molecules with short half-lives and long market lives, devices are often complex durable equipment with short market lives.”6 In fact, the estimated life of many medical devices ranges from about 18 months to two years, while some products requiring large capital investments or long-term clinical data for market penetration have longer life cycles.7

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Though medical devices encompass an extraordinary range and diversity, they nonetheless share a number of traits with respect to how they are developed. Table 2 provides a listing of these medical device innovation traits.

Table 2
Medical Device Innovation Traits

- Iterative and incremental product development process
- Continued product innovation following introduction into clinical practice
- Product improvements through practitioner use and suggestions
- Product refinements drawn from advances in other industries
- Importance of user skill for product performance

Innovations in medical devices are not restricted to the premarket phase of their development. Instead, actual use of devices by practitioners in clinical practice often drives future refinements and improvements. Clinical adoption serves as the beginning of an iterative process of: feedback from medical practitioners, device redesign, use, and more feedback.

In addition, medical device refinements often result from advances in other industries—in materials science, bioengineering, molecular biology, and information systems, for example. This contributes to the evolutionary nature of medical device development, and it lends a degree of unpredictability to the process. The benefits and effectiveness of a particular device technology may change as it evolves, and important refinements in medical technology may result from innovations in distant fields and industries that cannot be foreseen.

This incremental and dynamic process of medical device innovation has shaped both the laws and the regulatory policies governing these products in the following ways:

- The number and variety of devices, as well as their varying risks and benefits, has led to a flexible classification scheme that groups devices within generic types and tailors the regulatory requirements and evidentiary standards to the generic type and the particular device in question.

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8 The Wilkerson Group found that: “Virtually all device developments have adopted technology developed by other industries, rather than conducting basic component research. Contributions have been made by the defense, computer, telecommunications, aerospace, chemical, materials, and medical research industries.” The Wilkerson Group, p. 16.
• Short product life cycles, continuous and incremental changes, and new materials and uses have demonstrated the importance of post-market surveillance studies and epidemiologic investigations of device performance in the marketplace.

• The key role in device performance played by practitioners and institutions, as well as an understanding of the limits of premarket review, has underscored the importance of user reporting of adverse incidents to FDA’s efforts to protect and promote the public health.

The next section of this document provides an overview of the key laws and Agency initiatives governing FDA regulation of medical devices, emphasizing the evolution of the 510(k) process to where it stands today.

4.0 FDA’s Regulatory Framework

4.1 Introduction

Under the 1938 Federal Food, Drug, and Cosmetic Act (the “Act”), FDA’s authority over medical devices was confined to the seizure of adulterated or misbranded devices in interstate commerce. Though FDA used its device authority “with vigor and determination” dealing with “a flood of fraudulent devices” in the following decades, this authority proved inadequate in the face of increasing device sophistication.\(^9\) By the 1960s, FDA officials became convinced of the need for premarket review of some new devices and realized that due to their unique nature, existing laws were not adequate to regulate the expanding range of medical devices.

In October 1969, President Richard Nixon endorsed giving FDA additional authority to require premarket clearance “in certain cases” for medical devices. He called for a thorough study of the matter by the Department of Health, Education, and Welfare, the federal agency which housed FDA. Dr. Theodore Cooper of the National Institutes of Health (“NIH”) was appointed chair of a study group on medical devices, nicknamed the “Cooper Committee,” which issued a report in September 1970 that “rejected the approach that had been included in most of the pending legislation of simply applying the new drug provisions of existing law to new medical devices. Instead, the report recommended a different regulatory approach, designed specifically to deal with the breadth and diversity of medical devices.”\(^10\)

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9 Norman F. Estrin (ed.), *The Medical Device Industry: Science, Technology, and Regulation in a Competitive Environment* (New York: Marcel Dekker, Inc., 1990), p. 21. The provisions of the 1938 law relating to adulteration and misbranding were basically the same for drugs and devices. The 1938 law contained a premarket notification requirement for drugs, but not for devices. See also Peter Barton Hutt, “A History of Government Regulation of Adulteration and Misbranding of Medical Devices.”

Finally, in 1976, the recommendations of the Cooper Committee were reflected in Congressional passage of the Medical Device Amendments of 1976, in which Congress gave FDA direct and comprehensive regulatory authority over medical devices; authority distinct from the authorities it had provided the Agency with respect to drugs.\(^\text{11}\) Recognizing the wide variety of medical devices, Congress charged FDA to classify—and regulate—medical devices according to their risk and the scientific knowledge that exists pertaining to risk mitigation.

At several points in the years following enactment of the 1976 Medical Device Amendments, Congress chose to expand, refine, and modernize the regulatory tools the Agency has at its disposal. Table 3 lists the most important laws governing FDA’s regulation of medical devices,\(^\text{12}\) and Figure 1 provides a timeline of important regulatory and legislative events described in this paper.

**Table 3**

<table>
<thead>
<tr>
<th>Year</th>
<th>Statute</th>
</tr>
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<tbody>
<tr>
<td>1976</td>
<td>Medical Device Amendments, P.L. 94-295</td>
</tr>
<tr>
<td>1990</td>
<td>Safe Medical Devices Act, P.L. 101-629</td>
</tr>
<tr>
<td>1997</td>
<td>FDA Modernization Act, P.L. 105-115</td>
</tr>
<tr>
<td>2002</td>
<td>Medical Device User Fee and Modernization Act, P.L. 107-250</td>
</tr>
</tbody>
</table>

**Figure 1**

Timeline of Important Regulatory Events

\(^\text{11}\) The Wilkerson Group, pp. 58-59.

\(^\text{12}\) In addition to the laws cited in Table 3, Congress also amended the medical device provisions of the Food, Drug, and Cosmetic Act in 1992 (by enacting the Medical Device Amendments of 1992) and 1996 (by enacting the FDA Export Reform and Enhancement Act of 1996).
The following sections further explain the major laws and significant events that shaped FDA device regulation and the 510(k) program.

4.2 Medical Device Amendments of 1976

The Medical Device Amendments of 1976 set in place FDA’s regulatory framework for medical device regulation. The approach lawmakers took toward medical device regulation was based on the central principle from the Cooper Committee’s September 1970 report—that no single form of regulation, like the requirements FDA used in its premarket review of drugs, would be appropriate for all medical devices.\(^{13}\) The Cooper Committee called for a system where regulatory controls were calibrated to the risk posed by specific devices, and where premarket approval was appropriate for only a small percentage of devices—those that posed the greatest risk and involved uncertainty in the appropriate means of ensuring safety and effectiveness. This could be done by assigning the various devices to different risk-based classes (see Section 4.3 for the classification scheme), which were each regulated in different ways.\(^{14}\) In this way, the extent of FDA regulation was directly related to the likelihood that the device was unsafe or ineffective.\(^{15}\)

Importantly, the law required only those devices that posed the most significant risk and scientific uncertainty relating to safety and effectiveness to undergo comprehensive premarket reviews involving clinical testing.\(^{16}\) In addition, Congress explicitly chose not to apply to medical devices the same evidentiary standard that existed for drugs in determining “safety and effectiveness.” The device evidentiary standard was made less burdensome in light of the unique nature of the medical device innovation process.

Although Congress has revisited the regulation of medical devices over the years and has had countless opportunities to increase FDA’s authority and refine the regulatory requirements, it has not determined it necessary to alter the fundamental approach to device regulation. In fact, all legislation subsequent to the Medical Device Amendments of 1976 is built on the original statutory foundation.

The 510(k) process requires manufacturers of medical devices to notify the Agency, at least 90 days in advance, of their intent to market a product in the US. The Agency

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\(^{16}\) In 1990, in the Safe Medical Devices Act, Congress increased the FDA’s post-market controls, and required FDA to review new iterations of low and moderate risk products, providing market clearance only to those determined to be as safe and effective as their predicate devices.
then determines if the product is exempt\textsuperscript{17} (subject only to the general controls of the statute), is as safe and as effective as a legally marketed device of the same generic type\textsuperscript{18} or that the device requires premarket approval.\textsuperscript{19} A new device found to be not substantially equivalent (“NSE”) is classified as class III and a substantially equivalent new device is classified in the same regulatory class, either class II or class I, as the device to which it is found equivalent. Therefore, the 510(k) process serves as a means to classify new devices.

It is estimated that over 90% of all medical devices that have been authorized to be marketed in the US have been evaluated and classified through the 510(k) process. This important regulatory program is too often misunderstood, and therefore mischaracterized, but has tremendous significance in the everyday lives of Americans. The 510(k) program has evolved over time through continual process improvement, with the oversight of Congress, the Inspector General’s office and the General Accountability Office, as well as through internal Agency initiatives, yielding an effective and efficient means to responsibly regulate the vast universe of medical devices.

4.3 The Medical Device Classification Scheme

Section 513 of the Act requires FDA to classify all medical devices intended for human use into one of three regulatory classes. These classes of medical products are assigned according to the extent of control necessary to assure the safety and effectiveness of each device. And, importantly, these classes determine the review process the manufacturer must complete in order to obtain FDA authorization for marketing—either the 510(k) process or the premarket approval (or “PMA”) review process. The PMA review process is required only for class III devices, those that pose the greatest risk or involve the most scientific uncertainty.

Put simply, class I applies to those devices that pose the lowest potential risk, and classes II and III apply to those devices that pose progressively greater potential risk.\textsuperscript{20} Table 4 provides details related to each regulatory class and examples of medical devices assigned to the three device classifications. About 30% of all types of medical devices are in class I; about 60% are in class II; and approximately 10% are in class III.\textsuperscript{21}

Class I devices are those for which “general controls,” such as registration and listing, quality system regulations (“QSR”) and labeling, are sufficient to assure safety and

\textsuperscript{17} Exempt devices are not subject to premarket notification requirements, i.e., they do not have to submit a 510(k) application.
\textsuperscript{18} Equates with substantial equivalence.
\textsuperscript{19} Equates with not substantially equivalent.
\textsuperscript{20} Munsey explains the classification system’s implications succinctly: “Devices were regulated as Class II devices only if Class I controls were insufficient, and regulated as Class III devices if controls in Class I and Class II were not sufficient.” Munsey, “Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years,” p. 166.
effectiveness. Class I products include devices such as tongue depressors and elastic bandages, which do not support or sustain human life and do not pose an unreasonable risk of injury or illness. While 510(k) is a general control, many of these devices are exempt from 510(k) requirements.\(^{22}\)

Class II devices typically pose greater risks than class I devices and are subject to general controls, as well as performance standards or “special controls” (if they exist).\(^{23}\) X-ray machines, endoscopes, and dialysis catheters are examples of class II devices. A few class II devices are exempt from 510(k) requirements.

Class III devices are those that are life-supporting, life-sustaining, or present a potential unreasonable risk of illness or injury. Class III devices include permanent implants, like pacemakers and heart valves, and devices that are not implants but are nevertheless of substantial importance in preventing impairment of human health, including excimer laser systems and ablation catheters. Only class III devices are subject to the demands of the PMA review process, where “safety and effectiveness” must be demonstrated on a device-by-device basis before FDA grants approval for marketing.\(^{24}\)

According to FDA, over 4,000 new, low-risk devices that are exempt from FDA premarket review are marketed each year; about 3,500 products are reviewed and approved for marketing by FDA under the 510(k) process, with about 8% of these products subject to special controls that require clinical evidence.\(^{25}\) As cited in the Center’s Office of Device Evaluation Annual Reports, for each of the fiscal years 1996 to 2003, there were between 50 to 80 high-risk or new technology (i.e., class III) devices receiving either approval or approvable letters under the PMA review process.\(^{26}\)

\(^{22}\) In 1997, Congress required FDA to exempt all Class I devices (with certain exceptions) and to exempt as many Class II devices as possible in order to focus review on higher risk products. See The Food and Drug Modernization Administration Act of 1997 Section 510(l) and 510(m)(1).

\(^{23}\) Authorization for “special controls” was made in the Safe Medical Devices Act of 1990. These “special controls” include performance standards, guidance documents, as well as post-market surveillance, device tracking, and other activities to provide a reasonable assurance of safety and effectiveness.

\(^{24}\) Gelijns, “Comparing the Development of Drugs, Devices, and Clinical Procedures.”

\(^{25}\) Feigal, Gardner, and McClellan, p. 191.

<table>
<thead>
<tr>
<th></th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Premarket Review Process</strong></td>
<td>510(k) - (Most Devices Exempt)</td>
<td>510(k) - (Few Devices Exempt)</td>
<td>Premarket Approval (PMA)</td>
</tr>
<tr>
<td><strong>Risk Profile</strong></td>
<td>Low</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td><strong>Existing Knowledge Base for Safety and Effectiveness</strong></td>
<td>Extensive</td>
<td>Extensive</td>
<td>Minimal - Extensive</td>
</tr>
<tr>
<td><strong>Applicable Regulatory Controls</strong></td>
<td>General Controls (i.e., Adulteration; Misbranding; Registration; Listing)</td>
<td>General Controls + Performance Standards/Special Controls*</td>
<td>General Controls + Performance Standards/Special Controls* + Premarket Approval (PMA)</td>
</tr>
<tr>
<td><strong>Data Requirements</strong></td>
<td>Descriptive Data (Specifications) Performance Testing as Needed</td>
<td>Descriptive Data (Specifications) + Performance Testing (e.g., biocompatibility testing, conformance to product-specific standards, shelf-life, shock and vibration, temperature cycling) Clinical Data as Needed</td>
<td>Descriptive Data (Specifications) + Performance Testing (e.g., biocompatibility testing, conformance to product-specific standards, shelf-life, shock and vibration, temperature cycling) Clinical Trials</td>
</tr>
<tr>
<td><strong>Design Controls under the QSR</strong></td>
<td>Exempt (with exceptions)</td>
<td>Apply</td>
<td>Apply</td>
</tr>
<tr>
<td><strong>Device Examples</strong></td>
<td>Tongue Depressors, Elastic Bandages, Gauze, Syringes</td>
<td>Medical Imaging Equipment, Endoscopes, Patient Monitoring Equipment, Dialysis Catheters</td>
<td>Implantable Products (e.g., heart valves, pacemakers), Ablation Catheters, Excimer Laser</td>
</tr>
</tbody>
</table>

*Requirement added by the Safe Medical Devices Act of 1990. Special controls can include promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents, recommendations, and other appropriate actions as the Commissioner deems necessary to provide assurance of safety and effectiveness.
4.4 Implementing the Medical Device Amendments

In the years following enactment of the Medical Device Amendments of 1976, FDA began the time and resource-consuming task of classifying medical devices into the risk-based system required in the statute. It also developed regulations for the general controls which were authorized in the new law and codified in the Code of Federal Regulations (“CFR”). 21 CFR Part 807 established procedures for registration of device establishments and listing of devices; Subpart E describes 510(k) procedures, including when a 510(k) submission is required and the types of information that must be included in each submission (on August 23, 1977). The 510(k) requirements were incorporated into the registration and listing regulation because they apply only to those manufacturers required to register. Good manufacturing practice regulations were set forth, and subsequently modified over ensuing years, as found in 21 CFR Part 820 (on July 21, 1978, and revised October 7, 1996 as the Quality System Regulation). Labeling regulations, which include the meaning of the words “intended uses”, were set forth in 21 CFR Part 801 (on February 13, 1976). Over time, regulations governing reclassification of devices, investigational device exemptions, medical device reporting (MDR), and PMA procedures were added, and the device classification process proceeded. The wide variation in the types and uses of medical devices added complexity—as well as time and cost—to the regulatory process and made uniform regulatory approaches quite difficult. 27

4.5 Congressional Oversight and Internal Initiatives

During an eight-year period, 1982-1990, FDA implementation of the 1976 device law was closely scrutinized (and criticized) by several Congressional committees and subcommittees. 28 In 1982, the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations took FDA to task for its failure to complete the classification of medical devices into the three risk-based tiers that had been called for in the 1976 law. The oversight subcommittee also criticized the Agency’s failure to establish performance standards for class II products. Terming the Bureau of Medical Devices (now CDRH) “the FDA’s Neglected Child,” the subcommittee chronicled the Agency’s shortcomings over the preceding six years in implementing the 1976 law, noting that it was under-regulating higher-risk devices and over-regulating non-critical devices, wasting its resources on non-risky devices. 29 The

27 Munsey, “Trends and Events in FDA Regulation of Medical Devices Over the Last Fifty Years,” pp.168-170.
29 “Less Than the Sum of its Parts,” p.10. The subcommittee conducted an oversight hearing on July 16, 1982. The subcommittee issued a report, “Medical Device Regulation: The FDA’s Neglected Child,” based on the 1982 hearing, and it initiated a subsequent subcommittee staff investigation of FDA shortcomings in device regulation that compromised the public health.
House oversight panel also judged that certain of the provisions in the 1976 law (e.g., the performance standards requirement) may have been impractical.\footnote{“Less Than the Sum of its Parts,” p.7.}

In 1984, the Center undertook an introspective effort and created ten Criticism Task Forces to study various Center activities and to recommend remedies for any problems that were found. Some of the improvements that were made as a direct result included exempting 104 generic types of class I medical devices from the requirements of 510(k) as well as expediting the review of 510(k) applications for those devices that are unquestionably substantially equivalent. A guidance document that formed the basis for the 510(k) process and how submissions are reviewed was a direct result of the work of the Premarket Notification Criticism Task Force. Memorandum: \#K86-3 \textit{Guidance on the CDRH Premarket Notification Review Program June 30, 1986} clearly delineated the purposes of the premarket notification program and equated “substantial equivalence” to “as safe and as effective as.”\footnote{\textit{Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program \#K86-3}. Issued June 30, 1986. \url{http://www.fda.gov/cdrh/k863.html}.} The purposes of the program are to identify those new devices that must be placed into class III and undergo either premarket approval or reclassification prior to marketing; classify new devices; and achieve marketing equity through equality in the level of regulation between pre-Amendment devices and new devices. The document defined “intended use” in terms of information contained in the proposed labeling; outlined the types of information that will be required in order for the 510(k) submission to be reviewed; and established guidance on points to be considered during the review to ensure consistency of decisions. It also provided guidance to the reviewer on how to evaluate devices that have new technological features. The information contained in this guidance document was later codified by Congress in the \textit{Safe Medical Devices Act of 1990}.\footnote{\textit{Premarket Notification - Consistency of Reviews \#K89-1}. Issued February 28, 1989. \url{http://www.fda.gov/cdrh/k891.html}.}

In the fall of 1986, the Government Accountability Office (“GAO”) began an extensive study that would last a year and would review FDA’s implementation of the 510(k) program. Requested by Congressman Henry Waxman, the final GAO report, issued on September 21, 1988, identified the consistency of 510(k) reviews as an area where improvement to the program was needed. In response to the recommendations, CDRH developed standard operating procedures (SOPs) to ensure the consistency of reviews throughout the organization.\footnote{The \textit{Safe Medical Devices Act} was signed into law on November 28, 1990.}

\section*{4.6 Safe Medical Devices Act of 1990}

The \textit{Safe Medical Devices Act} (“SMDA”) was passed by Congress and became law in late 1990, after more than three years of Congressional deliberations.\footnote{The \textit{Safe Medical Devices Act} was signed into law on November 28, 1990.} The reforms in this law were an attempt to remedy what was perceived as inadequate FDA implementation of the \textit{Medical Device Amendments of 1976}. The SMDA
substantially increased FDA’s post-market authority over medical devices, including the authority to recall devices that pose an unreasonable risk of harm to the public health, and corrected many of the criticisms of the Agency expressed during many years of congressional oversight.\textsuperscript{34}

The new law also dropped the explicit mandate for FDA to issue performance standards while retaining FDA’s authority to issue or recognize standards. Importantly, it also strengthened FDA’s approach toward devices reaching the market through the 510(k) process. Whereas the 1976 law permitted manufacturers to market “substantially equivalent” devices within 90 days after submission of the notification, SMDA prevented these devices from being marketed without an explicit clearance order from FDA.\textsuperscript{35} The law also confirmed FDA’s authority to consider devices that differed in their design or technological characteristics from products already on the marketplace as “substantially equivalent,” if they do not raise any new questions of safety and effectiveness and are shown to be as safe and effective as marketed products.\textsuperscript{36} This facilitated FDA’s ability to obtain any information necessary to make a substantial equivalence decision, even if this required a review period in excess of the originally designated 90 days. However, if the new device raised new questions of safety or effectiveness from the device to which it was compared, it would not receive a marketing authorization through the 510(k) process and would automatically be classified as a class III device subject to PMA. In essence, SMDA codified the substantial equivalence decision-making process for 510(k)s.

Performance standards that originally defined class II devices were changed to “special controls” that permitted FDA guidance documents and voluntary consensus standards to be used in addition to general controls to ensure safety and effectiveness. Originally deemed a regulatory safeguard that was required at the time of reclassification of a device in order to provide reasonable assurance of the safety and effectiveness of a new class II device, special controls guidance documents currently exist for many types of devices and clearly define the types and amount of information that FDA recommends be provided in 510(k) submissions. This includes detailed recommendations for pre-clinical or bench testing as well as clinical testing. Special controls guidance documents provide industry and reviewers with a means for ensuring consistency in submissions.

Additionally, FDA began to require that increasingly more 510(k) submissions contain clinical evidence in order to support the claim of substantial equivalence. As this trend continued, these 510(k) submissions have begun to more closely resemble PMA applications.\textsuperscript{37}

\begin{footnotes}
\item[34] In 1987, legislation was proposed by House Energy and Commerce Committee Chairman John Dingell (D, MI) and House Energy and Commerce Health Subcommittee Chairman Henry Waxman (D, CA). This proposed legislation, The Medical Device Improvements Act of 1987, passed the House of Representatives, but not the Senate.
\item[35] See The Safe Medical Devices Act Section 513(i)
\item[36] Merrill, “Regulation of Drugs and Devices: An Evolution,” p. 64. See also, The Safe Medical Devices Act Section 513(i).
\item[37] Merrill, “Regulation of Drugs and Devices: An Evolution,” p. 64.
\end{footnotes}
Finally, under SMDA, only legally marketed medical devices, which are not subject to PMA, can be cited for comparison for the purposes of substantial equivalence determinations.

4.7 Regulatory Slowdown: 1990-1994

The level of Congressional oversight on FDA matters had proved disruptive for CDRH in the years preceding enactment of the SMDA, siphoning off a substantial degree of management attention in order to respond to Congressional inquiries. The years following enactment of the 1990 device law placed even more strain on device Center resources as the organization fell victim to substantial criticism and suspicion. In 1990, it took CDRH an average of 98 days to review product submissions under section 510(k). By 1994, review times for 510(k) submissions had more than doubled to 216 days.38

In May 1993, the House oversight subcommittee released a comprehensive and highly-critical report on the organization and the management of CDRH, entitled “Less Than the Sum of its Parts.” As a result of the backlog that had reached its peak at the end of 1993, FDA implemented several new programs that were intended to improve efficiency while maintaining high scientific standards. These programs impacted both the 510(k) review process and the PMA review process and included “tier triage”, “refuse to file,” and “expedited review” policies. Tier triage allowed the Center to adjust the resources devoted to a submission based on its importance to public health, while “refuse to file” allowed FDA to reject submissions that did not include the basic information needed for decision-making. Expedited review allowed priority review for devices intended to treat or diagnose life threatening diseases that address an unmet medical need. These highly successful programs have largely achieved their goals and facilitated the elimination of a significant backlog in pending premarket submissions.

Following the elimination of the backlogs, CDRH anticipated that the increase in efficiency with which it processed 510(k) submissions could give rise to criticism regarding the quality of its decisions. In 1996 integrity memorandum #I96-1 510(k) Quality Review Program was issued.39 This document enhanced the scientific oversight of 510(k) reviews to ensure the integrity and fairness of the process and the scientific propriety of the decisions that are made.

Under CDRH Director Bruce Burlington (1993-1999), the Center had initiated many internal reforms—a significant “re-engineering” effort to rebalance the way it went about medical device regulation. Among many efforts undertaken by the 510(k) Process Reengineering Team, perhaps the most innovative was one that resulted in the document “The New 510(k) Paradigm.” This document introduced alternative approaches to demonstrating substantial equivalence other than a traditional 510(k)

submission. These include the “Special 510(k)” which relies on a manufacturer’s “summary of design control activities” from their Quality Systems program for certain types of device modifications, and the “Abbreviated 510(k)” which relies on declarations of conformity to voluntary standards or established special controls. Many of the Center’s self-initiated activities were codified into law by The Food and Drug Administration Modernization Act of 1997 (“FDAMA”).

4.8 FDA Modernization Act of 1997

The Food and Drug Administration Modernization Act of 1997 cleared Congress in early November 1997 and was signed into law by President Clinton less than two weeks later. According to the Senate Labor and Human Resources Committee, this reform legislation was needed “to strike a better balance between the need to ensure that products are safe and effective, on the one hand, and to facilitate the timely availability of new products, on the other.”40 It made the point that:

…we cannot afford an overly complex, bureaucratic, time-consuming, and expensive regulatory system. Nor can we afford an adversarial relationship between the FDA and the industries it regulates or an agency pursuing so many agendas that it lacks a clear-cut mission and sphere of responsibility.41

The law directed FDA to use the “least burdensome” means of demonstrating the substantial equivalence of products subject to 510(k) requirements, as well as the effectiveness of products subject to PMA requirements. Further, the law exempted the lowest-risk class I devices from 510(k) review processes and provided CDRH a means to exempt certain class II devices. It also called for FDA to expand the range of products eligible for the Agency’s third-party (accredited persons) review program, and required CDRH to develop a guidance document to clarify when a specific intended use reasonably falls within a general one and is therefore appropriate for review and clearance through a 510(k) submission.

Section 207 of FDAMA, “Evaluation of Automatic Class III Designation,” which amended the Act to add section 513(f)(2), permits manufacturers who receive a NSE (Not Substantially Equivalent) decision from FDA in response to their 510(k) submission to request designation as a class I or class II medical device as opposed to the automatic class III designation that is usually associated with the NSE determination. This provision, also known as “de novo” or “risk-based” classification, allows devices that may be dissimilar to legally marketed class I and II devices to be classified into class I or class II and cleared for marketing without undergoing the unnecessary rigors of premarket approval. It is intended to be applied to certain devices that have been classified as class III simply because they were found NSE to any

identifiable legally marketed device. The de novo process has served as a “pressure release valve” when a PMA review represents overregulation.

FDAMA also provided for the creation of Section 514(c) of the Act which authorizes manufacturers to use FDA-recognized standards to meet requirements and to submit a declaration of conformity to FDA. It also mandates that FDA will accept the manufacturer’s declaration of conformity to an FDA-recognized standard to meet a requirement, if the standard is applicable.

In advance of the enactment of FDAMA, FDA had issued guidance on the use of declarations of conformity to certain domestic and international consensus standards as a means to streamline review and ensure consistency in decision-making. This effort was codified by FDAMA and in March of 2000, the Center published guidance for industry and staff on the use of standards in substantial equivalence determinations. This new document was intended to clarify for industry and for reviewers the ways in which standards may be utilized to demonstrate substantial equivalence in 510(k) submissions and to move the agency towards international harmonization. Information regarding a device’s conformity with a recognized national or international standard assists in consistently characterizing aspects of a device and may serve to replace detailed comparisons between the new device and a legally marketed device in the specific areas covered by the standard. With recognition of more than 750 national and international standards, CDRH has demonstrated its commitment to the program with the September 17, 2007, issuance of updated guidance on the use of standards entitled Recognition and Use of Consensus Standards.

As a result of these reforms, the 510(k) process is accomplishing the ideal that Congress has established and has become a state-of-the-art risk management tool.

4.9 Medical Device User Fee and Modernization Act of 2002

Taking a page from the pharmaceutical arena, the medical technology industry entered into talks with FDA in early 2002 to consider a user fee program for medical devices. At that time, FDA’s prescription drug user fee program had just entered its second decade and was widely credited with adding efficiency and predictability to the drug approval process.

In return for user fees that would be used primarily for the hire of new device review staff, FDA committed to meet a series of stringent performance goals that would begin to decrease review times for innovative products by the year 2007. The Medical Device User Fee and Modernization Act of 2002 (“MDUFMA”) provided much needed resources to the 510(k) program and was approved by Congress with

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strong bipartisan support in the last hours before Congress adjourned for the mid-term Congressional elections in November 2002. It was signed by President Bush days later.

4.10 FDA Amendments Act of 2007 and Beyond

Signed into law on September 27, 2007 by President Bush, the Food and Drug Administration Amendments Act of 2007 ("FDAAA") amends the Act to revise and extend the user fee programs for prescription drugs and for medical devices and also affects many other regulatory programs. Set to expire on October 1, 2012, FDAAA reauthorizes medical device user fees through fiscal year 2012. Additionally, Section 221 of the law extends FDA’s authority to conduct third-party reviews of 510(k) submissions until 2012.

In March 2008, the Director of CDRH announced that FDA will require more comprehensive data to be included in 510(k)s for devices where the product’s intended use is similar but not quite the same as the legally marketed device, as well as for devices where the technology is different from the legally marketed device. This announced shift in direction illustrates the flexibility of the 510(k) program to effectively accommodate the wide range of devices that fall under its purview. In essence, the foundation of the 510(k) review process allows FDA to make adjustments in the program to meet new challenges.

The next sections will focus on the integrity and strengths of the 510(k) program as well as put to rest issues that have been raised by detractors of the program.

5.0 The Integrity and Strength of Today’s 510(k) Program

In 1976, Congress was faced with the somewhat daunting task of creating a regulatory scheme suitable for all medical devices. Recognizing the wide diversity of devices and unique aspects of device development that set them apart from drugs, they devised a regulatory system involving a risk-based classification system where the level of regulation, and therefore the level of FDA premarket review, is commensurate with the level of risk presented by the device. Were this not true, and were every medical device subject to the rigorous PMA process, there would be very few new and innovative medical devices entering the market and few or no improvements to marketed devices. Quite appropriately, today only those devices that pose the highest level of risk to the user and whose safety and effectiveness cannot be assured with general controls and special controls, when needed, are subject to the PMA process.

The 510(k) process is part of a much broader regulatory scheme designed to provide a reasonable assurance of the safety and effectiveness of class I and class II devices. It

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is a regulatory means of classifying a device and subsequently clearing it for marketing by demonstrating that the device is as safe and as effective as the other devices that comprise that generic type of device. It is a flexible process that builds on a knowledge base that expands over time. Section 510(k) of the Act is only one of a comprehensive set of general controls and special controls geared to ensure the safety and effectiveness of medical devices both before and after they are marketed. The general controls also include establishment registration and medical device listing; good manufacturing practices, as demonstrated by compliance with the QSR; labeling; medical device reporting and provisions against adulteration and misbranding. Special controls include performance standards, postmarket surveillance and product-specific and general guidance. Through general and any applicable special controls, data on device safety and use is systematically collected. This provides FDA with information on actual, clinical use of well-characterized medical devices on which to base regulatory decisions.

The vigor of the 510(k) process comes from the strong regulatory framework of laws, regulations, and guidance documents that govern it. The Federal Food, Drug, and Cosmetic Act forms the foundation for the program and has been implemented through regulations and explained through agency-initiated program guidance. All in all, the framework for the 510(k) program depends heavily on the general controls and any applicable special controls and the flexibility that the controls have to meet the demands of evolving medical technology and an industry that excels in innovation. The concept of substantial equivalence accommodates new uses for “old” technology, as well as the advances associated with new technological innovation.

FDA guidance documents provide for consistency in the amount and type of documentation provided in submissions, as well as in how submissions are reviewed and decisions are made. CDRH has numerous general guidance documents that inform industry and FDA employees on procedures for providing additional information, making changes to existing devices, determining the intended use of a device, and the format for traditional and abbreviated 510(k)s. There are also numerous product-specific guidance documents that provide details on testing that is suggested for certain types of devices, for example implanted infusion ports or hydroxyapatite-coated orthopedic implants. Many of these product-specific guidance documents include recommendations for the inclusion of clinical data in 510(k) submissions.

As the regulatory body charged with medical device regulation, FDA has been granted a great deal of latitude, within a strong regulatory framework, to manage the

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510(k) program. Although the program is governed by regulation and the burden associated with the requirement for FDA to provide notice and comment in rule-making, there is considerable flexibility in the regulatory requirements of 21 CFR Part 807 pertaining to the information required for decision-making, the format and content of a 510(k) submission, and the criteria for taking actions and rendering decisions. CDRH has the discretion to determine the amount and type of data that can be requested of a submitter in order to be able to make a substantial equivalence determination. This includes the ability to require valid scientific evidence from a prospective clinical trial, if necessary, to ensure that the new device is as safe and as effective as the legally marketed device to which it is compared. FDA also has the power to determine, based on the proposed intended use, the device’s technology, and the data supplied, if the device raises new types of safety and effectiveness questions, compared to the proposed generic device type, and is therefore subject to PMA approval. Finally, FDA has the authority to decide whether a 510(k) submission meets requirements and thus determine whether the device can be marketed.

Importantly, the regulations allow for the healthy evolution of device technology. FDA has the ability to decide if scientific methods exist that are adequate to address questions regarding the safety and effectiveness of a device. Through this process, FDA is allowed to exercise reasonable scientific judgment in making decisions. This is essential in facilitating the availability of innovative medical devices to the American public.

6.0 510(k) Myths vs. Facts

The 510(k) program has been both misunderstood and mischaracterized by its critics almost since its inception. Most of the criticisms, however, are attributable to misinformation disseminated by a relative few who do not understand or appreciate the flexibilities of the program and its strengths. This section identifies some of the most common myths relating to the 510(k) program along with the facts regarding how the program works in reality.

Myth #1: Substantial equivalence involves showing that a new device is similar to an old and outdated product on the market before May 28, 1976.

Fact: This is perhaps the most common misunderstanding of the 510(k) program that results in unwarranted criticism. In reality, it is extremely unusual by today’s standards for a new device to go to market with a comparison to a 30-year-old device. The majority of today’s 510(k) clearances result from comparisons to today’s state-of-the-art technology. While it is true that Section 510(k) initially envisioned that products compared to a medical device on the market prior to enactment of the 1976 Medical Device Amendments could be marketed after being determined to be “substantially equivalent” SMDA amended the law to refer to comparisons to “legally marketed devices.” SMDA also established that a new device can not be found
substantially equivalent to a device that has been deemed misbranded or adulterated and removed from the market. Additionally, FDAMA authorized FDA reliance on national and international consensus standards which usually reflect state-of-the-art test methods developed to assess the latest in device technology. This evolution in the program, coupled with FDA’s authority to require virtually any data necessary for decision-making, has made the 510(k) program one of the most progressive premarket review programs in FDA. Perpetuating this notion that new devices are simply compared to older devices as a means to market does a considerable disservice to the 510(k) program and undermines the program’s true value and contribution to the protection of the public health.

**Myth #2:** The 510(k) program is a “quick and easy” way for manufacturers to get their product into the market.

**Fact:** The 510(k) program has been designed to provide a flexible means to appropriately regulate a wide variety of medical devices, and places appropriate regulatory requirements where necessary. Contrary to what some detractors espouse, today’s 510(k) program is anything but a “quick and easy” way to market. While 510(k)s for the simplest of devices (e.g., syringes) may experience a streamlined evaluation, consuming less than 90 days of FDA review, any greater degree of regulatory burden would represent a waste of FDA resources with little to no public health benefit. Likewise, modifications to legally marketed devices may be eligible for a review of less than 90 days, but again, the rigor of FDA’s evaluation matches the potential impact of the modification on the safety and effectiveness of the device and relies heavily on the design control provisions of the Quality System Regulation (QSR). For devices that represent significant changes in intended use or involve changes in technology, it is not uncommon for review times to exceed 90 days and require several rounds of FDA review. From a perspective of difficulty and scientific rigor, simple devices may go to market based on a comparison of specifications, but as a device’s public health significance, technological complexity or risk increases, so does the scientific demands imposed by FDA’s reviews. Today, it is common for 510(k) submissions to be based on batteries of non-clinical tests, including testing against national and international consensus standards. Further, it is not uncommon for FDA to require clinical evidence to support certain decisions where this level of scientific rigor is warranted. The necessity for clinical evidence is not solely dependent on the class of the device but is instead derived from the risk analysis that is conducted as part of the design validation aspect of design controls. Manufacturers of class II and class III devices are responsible for complying with design control requirements under the Quality System Regulation. They are therefore responsible for conducting a risk analysis and determining the amount of supporting data, preclinical and clinical, necessary for the premarket submission and maintaining it in the design history file for FDA inspection. The bottom line is that there are instances where the demands of today’s 510(k) review process becomes a barrier to market entry that some companies do not have the ability or financial resources to overcome.
Myth #3: Device malfunctions and patient injuries result from devices undergoing 510(k) review and serve as evidence that all devices should undergo the rigors of premarket approval to ensure their safety and effectiveness.

Fact: There are many reasons why critics of the 510(k) program argue that all devices should receive premarket approval. Device malfunctions that result in patient injury and device failures discovered in the postmarket period are frequently cited in support of the argument that all medical devices should follow the PMA process. One oft-cited example of a presumed “failure” of the 510(k) process is the Vitek TMJ implant. Five years after clearance of the device, FDA became aware of complaints of injuries attributed to the deterioration of the device material. Subsequently, FDA issued a letter citing good manufacturing practices (“GMP”) and medical device reporting (“MDR”) violations. Based on this unfortunate experience, it has been inferred that had the device been regulated through the more rigorous PMA program, the failures would not have occurred. This line of thinking is simply flawed. Manufacturing problems can only be addressed through robust quality systems, not paper reviews that are conducted at FDA headquarters. Likewise, clinical evaluation in the premarket period cannot identify or predict all problems that may occur when a device is made commercially available and placed in widespread distribution.

Further, the long-term effects of devices will never be fully identified and problems eliminated by clinical evaluation in the premarket period, whether the FDA review is through the PMA or 510(k) processes. In essence, the experience cited by the program’s critics is independent of the pathway to market.

Most importantly, the 510(k) program is only one of many regulatory controls FDA has in place to ensure the safety and effectiveness of medical devices, regardless of their path to market. In addition to obtaining FDA authorization to market a new device, manufacturers must comply with the other general controls including good manufacturing practices through the Quality Systems Regulation and medical device reporting, as well as any special controls. Special controls may include performance standards, guidance documents, post-market surveillance, device tracking, and other activities needed to provide a reasonable assurance of safety and effectiveness.

Myth #4: The Third Party Review Program that is available for select devices subject to 510(k) is an “easier” path to market that avoids FDA review.

Fact: Following enactment of FDAMA, FDA has accredited a number of independent third party review organizations to perform the premarket review of select class I and class II devices subject to 510(k) requirements. Like the 510(k) process, the “Accredited Persons Program” is misunderstood and misrepresented and has been a source of unfair criticism. While it is true that this program may speed up the review process, any increase in efficiency is largely attributable to the fact that the review commences immediately upon assignment and usually does not languish in a
queue. The premarket review is not conducted by less qualified review scientists. Also, contrary to statements related to the program, including some made to Congress, FDA remains responsible for the final decision and the overall process is no less stringent than one conducted internally by FDA’s review scientists.

7.0 Conclusion

The Medical Device Amendments of 1976 ensure that medical devices are appropriately regulated by creating a risk-based and science-driven classification system. Through continual process improvement, the regulation of medical devices is based upon a system that ensures their safety and effectiveness while focusing on the least amount of regulation sufficient to accomplish the purpose. For many low- and medium-risk devices, proper regulation depends on the 510(k) process.

The FDA’s 510(k) process for medical devices is of critical importance in ensuring the proper degree of regulation of all medical devices. Contrary to misconceptions, the 510(k) program is not simply a means to allow devices onto the market that are equivalent to “grandfathered” devices of the past. Today’s program successfully governs the vast majority of medical devices, offering FDA significant discretion to apply the necessary degree of regulation to ensure that new devices are safe and effective. The ability to request clinical trial data or efficiently create a new device classification through the risk-based or “de novo” program are examples of the immense flexibility and strength of the program.

The 510(k) program is an efficient means to appropriately regulate today’s diverse medical technology. Most importantly, the 510(k) program facilitates technological innovation by allowing for, and not over-regulating, improvements or advances in technology that lead to cost savings and better prevention, treatment, and diagnosis options for the American public. The program has been successful in allowing medical device innovation while still protecting the public health. It has evolved over the years into the form it takes today and, through continual process improvement, will continue to provide an appropriate path to market for devices whose risks are known and whose mitigation measures are well understood, while allowing for the innovation in medical technology that is of great benefit to our society.