The Changing Medical Device Regulatory Climate

Kenneth K. Kleinhenz

The Food and Drug Administration (FDA) is continuously evolving to meet the changing needs of the medical device industry, industry technologies, and the public at large. For example, prior to 1976, there were no specific laws to require premarket notifications of medical devices.1 Like the Thalidomide crisis in the 1960s, a series of safety issues, device failures, and patient deaths raised concerns, prompting Congress to enact legislation to protect the public from unregulated devices. Hence, the 510(k) and PMA (Premarket Approval) systems were enacted on May 28, 1976, changing the regulatory landscape for medical device manufacturers and initiating a 510(k) regulatory system based on predicate devices and substantial equivalence.

Since the launch of the newly created medical device approval system in 1976, many other countries have created systems to regulate medical devices. Some countries, such as Canada and Japan, have followed the U.S. and created hybrid regulatory models for low-risk devices. These hybrid systems follow the essential principals of the 510(k) system in recognizing the value of predicate devices and substantial equivalence as a means to streamline the regulatory process for low-risk medical devices that have historical precedents of safety and efficacy.

Since 1976, Congress and FDA have made other modifications to the 510(k) system, introducing such concepts as “the least burdensome approach” and authorizing cost-sharing strategies that allow FDA to charge fees for various premarket applications. These FDA “user fees” have funded additional FDA personnel to accelerate the review process for premarket authorizations and clearances of medical devices. A summary of the major changes to the food, drug and medical device laws and the driving forces behind such changes are outlined in Table 1:

Table 1. Major FDA Laws Related to Food, Drugs and Medical Devices

<table>
<thead>
<tr>
<th>Law</th>
<th>Year</th>
<th>Reason for Enactment</th>
<th>Major Changes</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Act</td>
<td>1906</td>
<td>Unsanitary meatpacking plants</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Food, Drug and Cosmetic Act</td>
<td>1938</td>
<td>Elixir Sulfanilamide tragedy</td>
<td>Premarket approval of drugs</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Authority to remove devices that are adulterated or misbranded</td>
<td></td>
</tr>
<tr>
<td>Kefauver-Harris Drug Amendment</td>
<td>1962</td>
<td>Thalidomide tragedy</td>
<td>Introduced efficacy as a new requirement to a New Drug Application (NDA)</td>
<td>3</td>
</tr>
<tr>
<td>The Medical Device Amendment of 1976</td>
<td>1976</td>
<td>Faulty IUD and Faulty pacemakers</td>
<td>Classification system of class I, II &amp; III 510(k) system for class I and II devices</td>
<td>2</td>
</tr>
</tbody>
</table>
### The Food and Drug Administration Modernization Act of 1997

The Cato Institute captured the essence of the dark times at the FDA in the early 1990s when it stated, “The Agency was in crisis mode.” Stung by pervasive criticism from Congress and the news media, FDA personnel hunkered down, trying to protect themselves by avoiding anything, including product approval, that might expose them to further censure. As the staff report of Dingell’s subcommittee observed, “reluctant to make a decision that may result in criticism from FDA management or from the outside, some reviewers make endless requests for information from applicants to avoid doing so.” In addition, David Kessler had become commissioner in November 1990, an appointment prompted by scandal. He was shaking up the organization with new appointments, reassignments and a new agenda, featuring unprecedented emphasis on aggressive enforcement and more stringent regulation. The unsettled situation in 1991 and 1992, which produced a “devastating slowdown in device clearances,” was aptly described as “chaos in U.S medical device regulation. In the midst of turmoil, late in 1991, a new storm struck: the furor over silicone-gel-filled breast implants.”

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>Safe Medical Device Act (SMDA)</td>
<td>FDA initiated requirement to be determined substantially equivalent for 510(k) versus notification only</td>
</tr>
<tr>
<td>1997</td>
<td>Food and Drug Administration Modernization Act (FDAMA)</td>
<td>Introduces “least burdensome approach”</td>
</tr>
<tr>
<td>2002</td>
<td>Medical Device User Fee and Modernization Act (MDUFMA)</td>
<td>Establishes user fees</td>
</tr>
<tr>
<td>2005</td>
<td>Medical Device User Fee and Stabilization Act (MDUFSA)</td>
<td>Modifies small business cap from $30 million to $100 million</td>
</tr>
</tbody>
</table>
FDA stepped up its activities and became openly hostile to industry. The Cato Institute reported, “With Kessler’s arrival, aggressive enforcement moved to the top of the Agency’s agenda.” The new commissioner delegated more enforcement authority to the district offices and encouraged them to use it. Compliance officials encouraged a philosophy of “act now, talk later.” District offices responded by finding more GMP violations, issuing more warning letters, and increasing the rate of other enforcement actions. Says former FDA chief counsel Peter Baron Hutt, “The more enforcement actions, the more FDA employees showed they were protecting the public health... The correlation, however, was spurious. There was no evidence that products became any safer as a result of the FDA’s stepped-up compliance program.”  

Even more alarming than the increased enforcement activities was the FDA’s new policy of denying product approvals and clearances solely because of Good Manufacturing Practice (GMP) compliance violations found on routine field inspections. The Cato Institute reported that, “The most perplexing enforcement initiative was the FDA’s adoption of a ‘reference list,’ known in the industry as the ‘black list,’ in April 1992. The FDA places on the list companies at which inspectors have identified ‘serious uncorrected or unresolved violations’ of GMP or, in about five percent of cases, other regulations. The FDA then refuses to process applications from those firms for 510(k) notifications and certain PMA supplements. Every company issued a warning letter is put on the list, but others also may be. The number of companies on the list quickly grew to about 600. The FDA gives no notice to a company when it is placed on the reference list, and the criteria for removal are vague.”  

The Food and Drug Administration Modernization Act of 1997 (FDAMA) addressed criticisms of the FDA’s overzealous and protracted product approval process. According to the Cato Institute, “For years prior to the enactment of the new law (FDAMA), the medical device industry was facing increasing development and review times, which threatened the viability of the industry. Review times were far in excess of statutory time frames. Manufacturers were faced with inconsistent, unpredictable and overly burdensome requirements. Unacceptable bureaucratic hurdles abounded in the system.” Among other things, FDAMA mandated the FDA to require only relevant information during the review process. This “least burdensome approach” sought to shift the FDA staff from overcautious self-preservation to a focus on customer service. As a result, significant backlogs of product reviews alleviated over time.  

Following the enactment of FDAMA, the FDA began to change its culture from an organization of obstacles to an organization of assistance. The Agency recognized that it did not have enough personnel to meet the goal of timely reviews. As a means to bridge this gap, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was enacted to facilitate more funding for the Agency through a cost-sharing approach with industry. The FDA established a schedule of fees based on the amount of resources required to review a filing. For example, the 510(k) filing fee was a few thousand dollars, while a PMA filing fee was tens of thousands of dollars. A new spirit of cooperation between FDA and industry emerged as FDA warning letters decreased and approval times shortened. The FDA and industry were once again working in a spirit of mutual trust and respect. Enactment of the Medical Device User Fee and Modernization Act (MDUFMA) in 2002 and the Medical Device User Fee and Stabilization Act (MDUFSA) in 2005 continued to build on this spirit of cooperation.  

The Pendulum Swings  
Recognizing the history and motivations for many of the changes and modifications to the Food and Drug Administration’s device regulations, newly proposed changes by the FDA to
the 510(k) system might appear to be founded less in true public health issues and more in issues of perception and misunderstanding, as outlined below.

In October 2008, a group of reviewers from the Center for Devices and Radiological Health (CDRH) wrote a letter to Congressman John Dingell complaining about CDRH management. Specifically, the reviewers stated:⁷

This letter seeks your urgent intervention because serious misconduct by management of the U.S. Food and Drug Administration (FDA) at the Center for Devices and Radiological Health (CDRH) is interfering with our responsibilities to ensure the safety and effectiveness of medical devices for the American public and the FDA’s mission to protect and promote the health of all Americans. Managers at CDRH have failed to follow the laws, rules, regulations and Agency Guidance to ensure the safety and effectiveness of medical devices and, consequently, they have corrupted the scientific review of medical devices. This misconduct reaches the highest levels of CDRH management, including the Center Director and Director of the Office of Device Evaluations (ODE).

In direct response to the October 2008 letter, Congressman Dingell wrote a letter to Andrew von Eschenbach, FDA Commissioner, in November 2008. Congressman Dingell’s letter to the FDA Commissioner stated:⁸

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have been investigating the ability of the Food and Drug Administration (FDA) to protect the American public from unsafe food, drugs and medical devices. As part of that inquiry, we have recently received compelling evidence of serious wrongdoing in connection with FDA’s review, clearance and approval process of medical devices. In particular, we are deeply disturbed by documents we received on October 14, 2008, from a large group of scientists and physicians working in the Center for Devices and Radiological Health (CDRH), who report misconduct within CDRH that represents an “unwarranted risk to public health and a silent danger that may only be recognized after many years.”

Is the pendulum swinging back to the sentiments of the 1990s, when the FDA adopted an adversarial relationship with industry under the auspices of protecting the public health? Since November 2008, FDA has steadily increased its actions against physicians and industry in the form of a more aggressive regulatory enforcement. The Center for Integration of Medicine and Innovative Technology (CMIT) reported in 2009:⁹

Agency leadership has made clear its intention to increase its oversight of FDA-regulated industries in the coming years. Reflecting these new priorities, in the first six months since Hamburg’s confirmation, the Agency’s new senior management has made good on its promise, both by closely examining premarket activities at FDA, as well as ramping up enforcement efforts. As the Agency moves forward with these initiatives, the medical device industry should be prepared for continued scrutiny and tougher regulation.

In an August 6, 2009 speech, Commissioner Margaret Hamburg set forth new, aggressive policies:¹⁰

Reports have noted that there has been a steep decline in the FDA’s enforcement activity over the past several years. At the same time, many of the enforcement actions that the FDA has undertaken have been hampered by unreasonable delays... We are fixing these pathways to improve the effectiveness of our enforcement system. Today, the FDA is taking several initial steps in this direction.
First, the FDA will set post-inspection deadlines. When the FDA finds that a firm is significantly out of compliance, we expect a prompt response to our findings. Once the FDA provides inspection findings identifying a serious problem, the firm will generally have no more than 15 working days in which to respond before the FDA moves ahead with a warning letter or enforcement action. This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action.

Second, the FDA will take responsible steps to speed the issuance of warning letters. I have approved a new policy brought forward by the FDA’s Chief Counsel to limit warning letter review to significant legal issues. As a result, most enforcement letters will be able to move forward through a more streamlined process. This approach is consistent with the FDA’s longstanding historical practice.

Third, the FDA will seek to work more closely with our regulatory partners to develop effective risk control and enforcement strategies. In many food safety cases, for example, local, state and international officials have more authority to take action quickly than the FDA. When the public health is at risk, the FDA will reach out to our partners to take rapid action while we alert the public and prepare longer-term responses.

Fourth, the FDA will prioritize enforcement follow-up. After a warning letter is issued or a major product recall occurs, we will make it a priority to follow up promptly with appropriate action, such as an inspection or investigation, to assess whether or not a company has made required changes in its practices.

Fifth, the FDA will be prepared to act swiftly and aggressively to protect the public. The FDA will no longer issue multiple warning letters to noncompliant firms before taking enforcement action. If we find that we must move quickly to address significant health concerns or egregious violations, we will consider immediate action — even before we have issued a formal warning letter.

Expediting the FDA’s warning letter process is sensible, but reducing legal oversight to do so is problematic. Reduced legal oversight will lead to unjustified warning letters. Recipients will eventually have the opportunity to contest them in court, but, in the meantime, the letters will hang over their heads like the “black list” of the 1990s. An FDA warning letter is a public document issued by an authoritative branch of the government that alleges some type of serious wrongdoing. The public’s presumption is that FDA would not issue such a letter without due cause. While the company waits for its day in court, its competitors and the media may unjustly vilify the company, causing significant harm to the organization in the form of lost sales and lost credibility. This new policy of reducing legal oversight of FDA warning letters reverses an FDA policy instituted on November 29, 2001, to ensure legal sufficiency and consistency with FDA policy, and to maintain credibility with the courts and industry as a whole because full legal review signals that FDA is prepared to defend a warning letter in court should it be challenged. The FDA’s new policy may indicate that speed and quantity are more important than quality and fairness. It is likely that some warning letters will be challenged in the courts, an unwelcome prospect for all parties.

The number of FDA warning letters rose dramatically from 1998 to 2001, until the November 2001 legal-review policy reversed the trend. Figure 1 shows that the number of FDA warning letters is increasing again since the low point in 2007. An increase in warning letters may be justified, but not if the increase is due to unwarranted warning letters. Given that the new policy was announced in 2009, after the number of warning letters began to rise in 2007, it appears that the new policy was implemented before the commissioner publically disclosed the Agency’s new approach.
The newest proposed changes to the FDA medical device regulations are outlined in a 2010 CDRH (Center for Devices and Radiological Health) document entitled, “CDRH Preliminary Internal Evaluations – Volume I and Volume II.” This proposal outlines several initiatives that the FDA is considering as a means to modify the 510(k) system and is, “in response to accusations that scientific decisions on product approvals have been inappropriately overturned by CDHR leadership.” Therefore, it is no coincidence that the 2010 proposed changes to the 510(k) system relate, in part or in whole, to the FDA reviewers’ letter to Congressman Dingell in 2008. Having established that the new stated policy of FDA is to vigorously regulate industry, the upward trend in FDA warning letters could be viewed as objective evidence toward this goal.

A greater regulatory burden may loom ahead for the industry should some or all of the proposed changes to the 510(k) system occur. For example, the FDA is considering splitting the class II category of devices into class IIa and class IIb subgroups. Approval requirements will stay the same for class IIa devices but become more stringent for class IIb devices. (The European Union (EU) uses a class IIa and class IIb system that is based on risk. However, the difference in regulations between the class IIa and class IIb EU products is not significant and consists only of the amount of regulatory oversight regarding technical file sampling plans.) According to the FDA, “Potential candidates for this device subset (IIb) may include implantable devices, life-sustaining devices, and life-supporting devices, which present greater risks than other class II device types.” The FDA has not yet defined the terms “life-sustaining” and “life-supporting,” so it is not clear where the line will be drawn between class IIa and class IIb. Without clear definitions, industry may be
subjected to arbitrary decisions and carry the burden of demonstrating that the device under review should not be subjected to the additional class IIb requirements. Given the current policy environment, class IIb might include most or all implantable devices.

According to CDRH, approval requirements for class IIb devices might be onerous and arbitrary:

...clinical information, manufacturing information, or, potentially, additional evaluation in the postmarket setting, would typically be necessary to support a substantial equivalence determination. CDRH should make clear that the delineation between class II and class IIb is meant to be a general guideline only. The types of evidence described below may at times be required for a device that was previously in class IIa but for which the Center has changed its evidentiary expectations on the basis of new scientific information.

Other FDA proposed changes to the 510(k) system involve replacing the long-standing 510(k) clearance process of a substantial equivalent determination with limitation (SE with limitation) with a new approach:

...pursuing a statutory amendment of section 513(i) (E) of the FDCA that would provide the Agency with express authority to consider an off-label use, under certain limited circumstances, when determining the “intended use” of a device under review through the 510(k) process. Such circumstances would include the availability of compelling evidence that the primary use of the marketed device will be off-label.

This approach sounds very limited, but implementation could give FDA broad discretion. It implies that the determination of a potential off-label use could require the company to provide safety and efficacy data (including formal clinical trials) for the possible off-label indication to obtain 510(k) clearance. This new authority could turn a class 2 product into a class 3 product, without the benefit of being able to market the product for the off-label indications. It would, in effect, force companies to perform clinical studies for indications that they are not seeking and without the benefit of obtaining the labeling claims. While this new approach would alleviate an FDA fear regarding off-label use, the new authority would, in essence, be regulating the practice of medicine by restricting market access to the device as a result of actual or suspected off-label activities by doctors. This new authority would allow FDA to restrict the activities of doctors by denying or restricting access to a medical device based solely on the doctors’ actions, which are regulated solely by the state in which he or she is licensed to practice medicine.

This shift in approach would introduce an arbitrary interpretation of the meaning of the key term, “compelling evidence,” introducing even more uncertainty into the 510(k) process. CDRH’s existing practices for off-label use are as follows:

CDRH’s primary mechanism for addressing anticipated off-label use is its authority to clear a device as “substantially equivalent with limitation,” thereby requiring, under certain circumstances, the manufacturer to include “a statement in labeling that provides appropriate information” regarding an off-label use... In order to make use of its SE with limitation authority, CDRH must consider: (1) whether there is “reasonable likelihood” that the device will be used for an intended use not identified in the proposed labeling for the device; and (2) if such use could cause harm.

Compared to the proposed changes that would allow FDA the authority to consider off-label use when reviewing a 510(k), the existing practice of SE with limitation is a balanced approach that mitigates the issue of potential off-label use without punishing doctors and/or industry for crimes it has yet to commit. Recognizing that only the rare
product has abused the system, these rare occurrences do not justify giving FDA broader authority to make arbitrary and speculative decisions on the intent of the doctor. These types of powers clearly cross the line between the role of the federal government and the states’ rights to regulate the practice of medicine.

Multiple and Split Predicates

FDA may change the concept of predicate devices, stifling innovation. Multiple predicates and “split predicates” may no longer be allowed:12

The term “split predicate” refers to a situation in which a 510(k) submitter is attempting to “split” the 510(k) decision-making process by demonstrating that the new device has the same “intended use” as one predicate and the same “technological characteristics” as another... Concerns have been raised that the use of a “split predicate” may not allow for a valid comparison of safety and effectiveness because no such device exists, either in part or in whole, and there is therefore no real-world information about its risk and benefits. There are differences of opinion among CDRH’s review staff regarding the validity of using a “split predicate,” which has led to inconsistency in the Center’s treatment of 510(k)s.

The FDA acknowledges that, “the submitter [in some cases] cites more than one predicate because no single predicate exists for the new device.”12 By allowing only one predicate device, the 510(k) system would eventually produce only “me too” products, as innovation would be stifled and eventually limited to yesterday’s technology. Limitations on the number of predicate devices would, in fact, create a self-fulfilling prophecy, as FDA has recently complained that pre-amendment-device predicates are too far away from the subject device: 12

“This determination (of substantial equivalence) becomes increasingly tenuous as the ‘distance’ (i.e., a device whose safety and efficacy were independently demonstrated) grows. In some cases, the ‘original’ predicate is a pre-amendment device that was classified on the basis of experience with the marketed device.”

However, the FDA currently has the authority to require clinical data to determine substantial equivalence in a 510(k) notification as, “eight percent of 510(k)s for non-in-vitro-diagnostic devices contain clinical data.”12

Moreover, if the restriction of “split predicates” had been enacted decades ago, there may not now be any risk of “distance between predicate devices” because 510(k) devices would have been restricted from introducing new technological aspects, forcing device manufacturers to pursue antiquated technologies through the years as a means to remain within the 510(k) system. Thus, reducing the risk of “distance between predicates” would be at the expense of innovation.

More troubling is the FDA proposal to restrict the use of “multiple predicates” in a 510(k) notification. FDA may have signaled that only one predicate device will be accepted in the future when it stated, “a submitter may cite more than one predicate in its 510(k), even when the substantial equivalence determination will rely on only one.”12 This comment underlines the subtlety of FDA, as it is stating that a company is free to reference more than one predicate device; however, FDA will likely, in essence, only recognize one of the predicates. Furthermore, the FDA suggested that 510(k)s that utilize multiple predicate devices are of lower quality and higher risk when it stated, “these data suggest that 510(k)s that cite more than one predicate may be associated with more adverse event reports, on average, than 510(k)s that cite only one.”12 The FDA’s rationale for their proposal to limit the number of predicate devices is due to an observation that there is an “apparent association between citing more than five predicates and a greater mean rate of adverse
However, it is important to note that the FDA report did not claim that the use of split-predicates or the use of multiple predicates resulted in unsafe devices. The FDA has also suggested that it will “consider developing guidance for when a device should no longer be available for use as a predicate because of safety and/or effectiveness concerns.” This policy is sensible, provided that the approval process for new technologies does not become onerous, as would be the case if the use of multiple and split predicates is unduly limited.

Also, the FDA is considering a proposal to expand its rescission authority for 510(k)s. To date, “FDA has largely limited is rescission of 510(k)s to situation[s] involving fraud.” However, CDRH is considering issuing “a regulation to define the scope, grounds and appropriate procedures, including notice and an opportunity for a hearing, for the exercise of its authority to fully or partially rescind a 510(k) clearance.” The FDA might use this new policy to rescind 510(k)s based on multiple, split, obsolete or rescinded predicates.

In September 2009, the FDA initiated a 510(k) task force and asked the Institute of Medicine (IOM) to establish a Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process to review the existing FDA 501(k) system. Remarkably, none of the 12 committee members represent industry nor appear to have any industry experience. Table 2 outlines key aspects of the 510(k) system that were delegated to the IOM to be considered for modification.

<table>
<thead>
<tr>
<th>Table 2. 510(k) Modification Proposals Delegated to the IOM Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action</strong></td>
</tr>
<tr>
<td>Rescission authority</td>
</tr>
<tr>
<td>Postmarket surveillance authorities</td>
</tr>
<tr>
<td>Establish a class IIb</td>
</tr>
<tr>
<td>Predicate clarification</td>
</tr>
<tr>
<td>Clarify and consolidate regulatory terms</td>
</tr>
<tr>
<td>Device review</td>
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<tr>
<td>Off-label use</td>
</tr>
</tbody>
</table>

**CDRH Self-Assessment**

In an admirable exercise of self-assessment, the FDA Working Group conducted a survey to measure CDRH personnel understanding of 510(k) regulations, guidance documents, and review practices. Participants included 215 CDRH reviewers and 21 ODE (Office of Device Evaluation) Branch Chiefs and Deputy Division Directors (managers). Each person was given a multiple-choice, open-book questionnaire, consisting of questions on 20 topics with 70 possible responses. As a whole, FDA review staff (n=215) provided incorrect responses.
28% of the time, while managers (n=21) provided incorrect responses 25% of the time. Rather than implementing new, problematic regulations, FDA could thus focus first on properly training its personnel to correctly interpret the current regulations.

Table 3 provides an example question about basic 510(k) rules. More than 40% of the FDA review staff and 14% of managers incorrectly understood the first option (extension of shelf life), despite the fact that the information is provided in simple flowcharts within an FDA Guidance document entitled, “Deciding When to Submit a 510(k) for a Change to an Existing Device”15 (Figures 2-5).

The survey investigated questions of expertise but did not directly address the letter CDRH reviewers sent to Congressman Dingell claiming that, “Managers at CDRH have failed to follow the laws, rules, regulations and Agency Guidance to ensure the safety and effectiveness of medical devices.”7,12 Nevertheless, it does prove that the reviewers have some of their own work to do.

Table 3. Example Question about Basic 510(k) Rules
(See notes below table.)

<table>
<thead>
<tr>
<th>Option</th>
<th>Reviewers % Selected (#)</th>
<th>Managers % Selected (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Extension of shelf life from 1 year to 5 years using methods described in the original 510(k).</td>
<td>40.1% (75)</td>
<td>14.3% (3)</td>
</tr>
<tr>
<td>B. Addition of a wireless communication feature.</td>
<td>94.7% (177)</td>
<td>95.2% (20)</td>
</tr>
<tr>
<td>C. Change from AC to battery power.</td>
<td>70.6% (132)</td>
<td>61.9% (13)</td>
</tr>
<tr>
<td>D. Dimensional specification changes.</td>
<td>56.2% (105)</td>
<td>47.6% (10)</td>
</tr>
<tr>
<td>E. Change in sterilization from gamma irradiation to ethylene oxide sterilization, with the same SAL (the material is not affected by the new sterilization method).</td>
<td>55.1% (103)</td>
<td>66.7% (14)</td>
</tr>
</tbody>
</table>

Notes on Table 4: Bolded responses have a correct answer of “yes,” meaning that 100% is a perfect response, while non-bolded responses would have a perfect response of 0%. The numbers in parentheses are the number of participants that responded in the affirmative for the question. Source: Appendix D of CDRH Preliminary Internal Evaluations – Volume I. “510(k) Working Group Preliminary Report and Recommendations.”12
Figure 2. Flowchart B (Part 1)

FLOWCHART B – IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?

From Main Chart

YES

B1

Control mechanism changes?

NO

NO

B6.3

Do results of design validation raise new issues of SAE?

YES

New 510 (k)

Documentation

15% – 40% WRONG

A

Figure 3. Flowchart B (Part 2)

FLOWCHART B – IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?

From Main Chart

YES

B1

Control mechanism changes?

NO

New 510 (k)

5% WRONG

B
Summary
The FDA has embarked on a thorough reassessment of its 501(k) system. Improvements in the quality and speed of Agency actions are always welcome. However, given recent FDA trends, publications and pronouncements, this reassessment could usher in a return to the
adversarial logjam of the 1990s. Improved training programs for FDA personnel appear to be a higher priority.

References

7. Letter Congressman Dingell from FDA Reviewer Staff, October 14, 2008.

Author

Kenneth K. Kleinhenz is VP, Regulatory Affairs & Quality Assurance at Cytori Therapeutics, Inc. Contact him at 1.858.458.0900 or kkleinhenz@cytori.com.