Introduction

The Medical Device User Fee and Modernization Act (MDUFMA or MDUFA) is a set of agreements between the Food and Drug Administration (FDA) and the medical device industry to provide funds for the FDA to review medical devices. Every five years, MDUFA must be reauthorized with adjusted fees and new guidelines that aim to streamline the review process. Industry leaders and the FDA are currently in discussions on proposals to include in MDUFA III as MDUFA II is set to expire on September 30th 2012.

Why is MDUFA Necessary?

Patients deserve to have access to the latest and most effective medical treatments, which requires the prompt approval of medical devices. In the years preceding the first iteration of MDUFA in 2002, the FDA was becoming increasingly burdened by the rapidly proliferating medical device industry and the influx of technologically advanced devices to their offices for review. With the enactment of MDUFA, device inventors paid user fees to provide resources for the FDA for premarket review of medical devices for safety and efficacy before they are approved for market. A portion of the user fees are also used by the FDA to inspect factories in which the medical devices are being made to ensure compliance with good manufacturing practices (GMP) among other requirements.

What is a Medical Device?

Due to the enormous variance of medical devices, it is important to establish a definition for medical devices. As defined by the FDA, a medical device is “An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

Key Takeaways

Growing uncertainty in 510(k) process
- Total elapsed time for the approval of a device through the 510(k) process has increased since 2005.

Industry and FDA disagreements
- The industry does not agree with the FDA’s proposed 17% increase in user fee collection to offset for inflation and projected spending.
- Due to the FDA’s inability to meet some of its performance goals from MDUFA II, the industry proposes a two-year reauthorization of the user fees.

Impending deadline
- Recommendation for the reauthorization of MDUFA III must be submitted to Congress by January 15th 2012.
Medical Device Classification and Regulatory Bodies

Two branches of the FDA are responsible for the review of medical devices: the Center for Devices and Radiological health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The vast majority of medical devices are reviewed by CDRH. If the primary action through which a combination drug-device product’s therapeutic properties are achieved cannot be primarily assigned to only the drug or only the device, the Office of Combination Products (OCP) of the FDA will assign the product for review at either CDRH or CBER. CBER reviews devices under a biological license application (BLA). CDRH requires the submission of either premarket notification (510(k)) or premarket approval (PMA) for review. Table 1 details the classifications of devices that the CDRH uses to determine which submission is required. The differences between 510(k) and PMA are elucidated in Table 2.

| Table 1: FDA Device Classifications

<table>
<thead>
<tr>
<th>Device Classification</th>
<th>Examples</th>
<th>Required Submission</th>
</tr>
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<tbody>
<tr>
<td>Class I (low-risk)</td>
<td>Elastic bandages, examination gloves, hand-held surgical instruments</td>
<td>Registration only unless 510(k) specifically required</td>
</tr>
<tr>
<td>Class II (moderate-risk)</td>
<td>Powered wheelchairs, infusion pumps, surgical drapes</td>
<td>510(k) clearance unless exempt; IDE possible</td>
</tr>
<tr>
<td>Class III (high-risk)</td>
<td>Heart valves, silicone gel-filled breast implants, implanted cerebella stimulators</td>
<td>PMA approval unless 510(k) exempt; IDE probable</td>
</tr>
</tbody>
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| Table 2: 510(k) and PMA Submissions

<table>
<thead>
<tr>
<th></th>
<th>510(k)</th>
<th>PMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard submission fee (2011)</td>
<td>$4,348</td>
<td>$236,298</td>
</tr>
<tr>
<td>Standard small business submission fee (2011)</td>
<td>$2,174</td>
<td>$59,075</td>
</tr>
<tr>
<td>Premarket inspection of manufacturing facility</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical data required?</td>
<td>Usually not required</td>
<td>Almost always required</td>
</tr>
<tr>
<td>Standard for approval</td>
<td>Substantial equivalence to predicate device</td>
<td>Review of scientific data</td>
</tr>
<tr>
<td>Timeline for decision (though actual time may be longer)</td>
<td>90 days</td>
<td>The FDA has 45 days to make sure that the application is complete before the PMA is filed. After filing, the FDA has 180 days to review after the PMA is filed.</td>
</tr>
</tbody>
</table>

1 IDE: Investigational Device Exemption; application to FDA that allows the use of a device in clinical trials.  
2 A device is found to be “substantially equivalent” to a predicate device if it performs the same functions and does not introduce issues of safety or efficacy.
PMA Supplemental Applications

Medical device companies must submit a supplemental PMA application if a device is altered in some way. Some examples of an alteration could include the use of a device to treat a different symptom or illness, change in construction materials, software change, or one of many other changes that is listed on the FDA’s guidance documents.

Discrepancy between FDA Time and Total Time Elapsed

After the FDA reviews a medical device under either 510(k) or PMA pathways, it may require more information. The time that the industry takes to respond to the FDA’s request for more information is called “industry time.” This is the cause of the difference between the total amount of FDA review time and the total elapsed time to approve of a device. If adequate information is not provided upon submission, the FDA may require two or more review cycles before approval. The FDA review times and overall elapsed review times have decreased for PMAs and PMA supplements since 2006. Although the FDA review time has remained constant for 510(k) applications, the average total time elapsed to approval has increased (Figure 1). This is strange considering the number of 510(k) submissions has remained relatively stable (Table 3). The causes of the increase in time are unclear, but this is a point of contention for the industry.

Figure 1: Average Time to 510(k) Decision

* Substantially equivalent and not substantially equivalent decisions only: averages may not sum due to rounding.
**2009 and 2010 cohorts still open as of July 5, 2011; data may change.
History of Medical Device User Fees

MDUFA I: Fiscal Year 2003-2007
The main purpose of MDUFA I was to provide the FDA with resources to fund its medical device review and regulatory processes. In addition to the user fees, MDUFA I instituted performance goals that provided a general time table for how long it would take the FDA to perform a particular action.

MDUFA II: Fiscal Year 2008-2012
Reduction of existing user fees, introduction of new user fees and more rigorous performance goal timelines are the main changes from MDUFA I.

The Future of MDUFA
The FDA, medical device industry and stakeholders are currently in discussions concerning the reauthorization of MDUFA III. The industry has proposed a two-year reauthorization of MDUFA III instead of the usual five-year reauthorization in order to allow the FDA to meet more of its performance goals from MDUFA II. One area that has the industry especially perturbed is the increased total elapsed time for 510(k) approvals. The CDRH is in the midst of an internal review of the 510(k) procedure to find ways to improve its transparency and efficiency. Another proposal that is up for debate is a 17% increase in user fees, which the FDA says is required to compensate for the increased workload due to the increased amount of pre-submission interactions with the industry. The Congressional Committee has stressed the importance of meeting the proposed January 15, 2012 deadline for recommendations on MDUFA III.

Table 3: 510(k) and PMA Submissions 2004-2009*

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
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<tr>
<td>510(k) Submissions</td>
<td>4458</td>
<td>4202</td>
<td>4810</td>
<td>4722</td>
<td>4415</td>
<td>3107</td>
<td>3130</td>
<td>3240</td>
<td>3192</td>
<td>3363</td>
<td>3597</td>
</tr>
<tr>
<td>PMA Submissions</td>
<td>64</td>
<td>67</td>
<td>71</td>
<td>49</td>
<td>54</td>
<td>37</td>
<td>43</td>
<td>35</td>
<td>31</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td>PMA Supplements</td>
<td>557</td>
<td>546</td>
<td>641</td>
<td>645</td>
<td>666</td>
<td>565</td>
<td>712</td>
<td>1113</td>
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Operation Healthcare Choice is the Forum’s public policy center focused on promoting high-value healthcare and higher quality health insurance that expands consumer choice. Operation Healthcare Choice experts conduct research, offer commentary, and develop policies aimed at eliminating healthcare’s burden on the economy.

References

i 75th Congress. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 §201(h)).


iii Adapted from ibid.

iv Adapted from Shuren J testimony found in Hearing on “Regulatory Reform Series #5 - FDA Medical Device Regulation: Impact on American Patients, Innovation, and Jobs.” July 20, 2011.


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