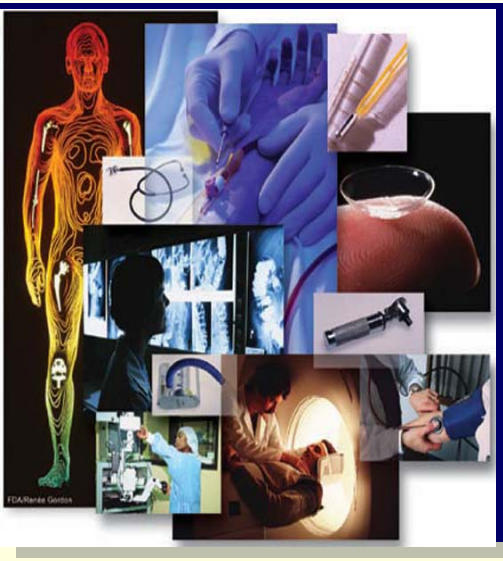

Update on 510(k) Paradigm

What is on the horizon?

Association of Medical Device Manufacturers

April 26, 2011

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Reviewer, Office of In Vitro Diagnostic Devices

OVERVIEW

- **Why reform?**
- **Steps Taken to Evaluate Program**
  - Institute of Medicine (IOM)
  - FDA Task Force on Science and Regulatory Decision Making
  - FDA 510(k) Working Groups
- **Implementation Teams**
- **MDUFA**
- **Summary**

WHY REFORM?
Device Regulation

Federal Food, Drug and Cosmetic Act (FD&CA) granted FDA authority to regulate devices

- May 1976
- 3 Risk Based Classifications
  - PMA
  - 510(k)
  - Future devices- Automatic class III Designation
    - Mechanism for reclassification
- 510(k) process
  - Allows for new technologies
  - Devices with a new indications (no predicate)- class III

Why reform
Are requirements commensurate with risk?

In addition to resources and time required for industry and FDA, cost is a factor.

2011 User Fees:

Cost of 510(k)	$4,348
Cost of PMA	$236,298

Unnecessarily stifling innovation?

New indications do not always mean high risk.

Why reform
1998 de Novo option created

- Prior to 1998, PMA if:
  1. 510(k) review ended in NSE b/c
     - performance not equivalent
     - or no predicate
  2. Automatic Class III Designation
- 1998 (FDAMA) amended Automatic Class III Designation
  - Section 513(f)(2)
  - New mechanism
- de Novo
  - No predicate & low to moderate risk
  - Petition for reclassification
  - If adequate evidence, classified as I or II
  - Burden is more “510(k)-like”
    - Cost
    - Post-market and manufacturing requirements

Why reform de Novo process

- The de novo process
  - Sponsor ***must*** submit a 510(k) and be issued NSE
  - Sponsor has 30 days to file Petition
    - During that 30 days- collect data (often clinical) to support Petition
  - When Petition is received, CDRH has 60 days:
    - Review the petition & make decision
    - Write Special Control guidance
    - Issue FR Announcement

Why Reform
Stakeholder concerns

- **Industry**
  - Inconsistent, unpredictable, too burdensome, transparency
- **FDA**
  - Not enough authority to get what we need, often make decisions with incomplete information
  - New technologies or “stretched” indications- challenging
- **Public**
  - Recalls, AEs

- Are we accomplishing our goals?
  - 35 year old regs
  - Optimizing resources & processes?
  - protect & promote public health?
- Impacts nearly 3500 510(k)s per year

STEPS TAKEN TO EVALUATE PROGRAM

How are we addressing these concerns?

Steps Taken To Evaluate Program

Three initiatives

- Institute of Medicine (IOM)
- FDA Task Force on Science and Regulatory Decision Making
- FDA 510(k) Working Groups

Steps Taken
Institute of Medicine

- Contracted to “assess whether the 510(k) process sufficiently and optimally protects patients and promotes innovation in support of public health”
- If not, recommend the legislative, regulatory or administrative changes needed

Steps Taken
Institute of Medicine

- Assembled a team of experts
- 3 Public Meetings- “Public Health Effectiveness of 510(k) Clearance Process” (March, June, July 2010)
- October- Released Workshop Report
  - Focused on challenges of balancing patient safety and innovation
- **FINAL Report mid-2011**

Peter Barton Hutt at OIM meeting

When asked if 1976 amendments should require more scientific evidence, he said there was no need.

- "FDA can require whatever data are needed…"

- "Trying to legislate the **level of evidence required** would…set the bar at the wrong place. It [can only be accomplished] by **individual reviewers case by case**."

Steps Taken
FDA Internal Groups

Two groups tasked with developing recommendations

- Task Force on the Utilization of Science in Regulatory Decision Making
  - Adapting to evolving science and new risk/benefit information, while maintaining predictability
- 510(k) Working Group
  - Improving the quality and consistency in reviews

Steps Taken
FDA Internal Groups

Formed subgroups- identified issues and potential solutions

Industry and public participation & comments

February 18, 2010- Public Meeting to provide input

- Divergent views from industry and consumers
- FDA summarized challenges:
  - growing complexity
  - speed of evolving technologies
  - **balancing predictability with flexibility**

Steps Taken
FDA's Preliminary Recommendations

Two reports totaling 55 recommendations published Aug 5, 2010

- Focused on:
  - Fostering innovation
  - Enhancing predictability
  - Improving patient safety
- By:
  - Improving processes
  - More guidance
  - Communications
  - Training
  - Leveraging expertise
  - Infrastructure
  - Regulatory changes

IMPLEMENTATION TEAMS

What are we doing with all these recommendations?

Implementation Teams formed to address recommendations in Public Report

Implementation Teams
Four types of activities

Within CDRH:

A. Guidance documents

B. Internal and administrative matters

C. Programmatic and regulatory

External:

D. Recommendations referred to IOM

- http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf

Implementation Teams Changes raise concern

- **FDA will:**
  - **Seek public comments, as appropriate**
  - **Public meeting prior to implementation**

Implementation Teams Guidance

A. Guidance documents

Three types of guidance initiatives

Guidance Updates

1. clarify what types of changes warrant a new 510(k) and which are eligible for a Special 510(k)
2. improve quality and performance of clinical trials
3. streamline the de Novo process
4. clarify appropriate use of consensus standards
5. provide information on how to enhance the quality of pre-IDE interactions
6. clarify the process for appealing CDRH decisions, including rescissions

Provide General Guidance that describes:

1. when clinical data is needed
2. when photographs or schematics are needed
3. appropriate use of multiple predicates
4. the criteria for identifying "different questions of safety and effectiveness" and technological changes that generally raise such questions
5. resolving discrepancies between the 510(k) flowchart and the FD&C Act
6. the characteristics that should be included in the concept of “intended use”
7. the development of 510(k) summaries to assure they’re accurate and complete

Additional device-specific guidances that may be provided

On a case-by-case basis:

1. when and what type of manufacturing data to submit
2. when a pre-clearance inspection would be conducted
3. when and what types of modifications should be periodically reported in lieu of submitting a 510(k)
4. when and what type of safety and effectiveness information should be submitted as a brief description

IMPLEMENTATION TEAMS

B. Internal and Administrative Matters

Internal and Administrative Matters
Five categories

1. **Establish a Center Science Council**
2. **Assess Center Staffing Needs**
3. **Enhance Training**
4. **Leverage External Experts**
5. **Improve Integration and Knowledge Management**

Internal and Administrative Matters
1. Establish a Center Science Council

1) oversee the development of process for determining and implementing a response to new scientific information

2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the program

3) periodically audit review decisions to assess adequacy, accuracy and consistency

4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants

Internal and Administrative Matters
2. Assess Center Staffing Needs

1) develop process for identifying, recruiting, retaining, and training needed staff

2) create mechanism- assemble an experienced ad hoc team to assist with unexpected surges in workload

Internal and Administrative Matters
3. Enhance Training

Develop and implement training on core competencies such as:

1) determining "intended use"

2) determining whether a 510(k) raises “different questions of safety and effectiveness”

3) the review of 510(k)s that use “multiple predicates”

4) how we assign product codes

5) the interpretation of the “least burdensome” principles

6) the appropriate use of consensus standards

Internal and Administrative Matters
4. Leverage External Experts

1) develop a network of external experts to leverage their scientific expertise

2) assess best-practices and develop SOPs for staff engagement with external experts

Internal and Administrative Matters
5. Integration and Knowledge Management

1) improve knowledge management across the Center

2) evaluate methods used to integrate device information into a dynamic format so that it can be more readily used by staff to make regulatory decisions

Implementation Teams

C. Programmatic and Regulatory

Programmatic and Regulatory 11 initiatives

1. "Assurance Case" Pilot
2. Providing Information
3. Postmarket Information
4. "Notice to Industry Letters"
5. IDE Process
6. Unique Device Identification (UDI) System
7. Multiple Predicates
8. Third-Party Review
9. Guidance and Regulation Development
10. Transfer of Ownership Regulation
11. Labeling

Programmatic and Regulatory

1. Implement an "Assurance Case" Pilot Program

To explore the use of an “assurance case” framework for 510(k) submissions

2. Provide Additional Information

To make device photographs available in a public database w/o disclosing proprietary information

Programmatic and Regulatory

3. Improve Collection and Analysis of Postmarket Information

- determine system requirements and select the platform for a new adverse event database
- develop better data sources, methods and tools for collecting and analyzing postmarket information
- enhance the Center's capabilities to synthesize evidence and quantitative decision making

Programmatic and Regulatory

4. Establish "Notice to Industry Letters" as a Standard Practice

Clarify how to quickly inform stakeholders when regulatory expectations change based on new information

5. Improve the IDE Process

Assess, characterize and mitigate challenges in IDE processes

Programmatic and Regulatory

6. Implement a Unique Device Identification (UDI) System

- permit rapid and accurate identification of devices
- improve adverse event reporting and identification of device-specific problems

Programmatic and Regulatory

7. Multiple Predicate Analysis

Conduct additional analyses to determine the basis for the apparent association between citing more than 5 predicates and a higher rate of AE reports

8. Clarify & Improve Third-Party Review

- develop a process for regularly evaluating the list of eligible device types
- enhance third-party reviewer training

Programmatic and Regulatory

9. Streamline Guidance and Regulation Development Process

Provide clarity, predictability, and efficiency in development process

10. Draft 510(k) Transfer of Ownership Regulation

Better document 510(k) transfers of ownership

Programmatic and Regulatory

11. Improve Medical Device Labeling

- develop an on-line labeling repository
- clarify the statutory listing requirements for the submission of labeling

IMPLENTATION TEAMS

D. Refer to IOM to explore and consider

Refer to Institute of Medicine Seven Issues

1. Rescission Authority
2. Postmarket Surveillance Authorities
3. Establish a Class IIb
4. Predicate Clarification
5. Clarify and Consolidate Regulatory Terms
6. Device Review
7. Off-Label Use

Refer to IOM

1. Rescission Authority

Define scope and grounds for exercising authority to fully or partially rescind a 510(k)

2. Postmarket Surveillance Authorities

Greater authorities to require postmarket surveillance as a condition of clearance

Refer to IOM

3. Establish a Class IIb & develop guidance

Define devices

where typically-

- clinical information
- manufacturing information or,
- potentially, additional post market evaluation is needed

4. Predicate Clarification

Clarify when a device should no longer be available as a predicate

Refer to IOM

5. Clarify and Consolidate Regulatory Terms

Consolidate concepts of “indication for use” and “intended use” into “intended use”

6. Device Review

Possibly requiring each 510(k) submitter to keep a device under review available upon request

Refer to IOM

7. Off-Label Use

Possibility of pursuing a statutory amendment that would provide express authority to consider an off-label use

Medical Device User Fees Amendments (MDUFA) Negotiations

What else might impact 510(k) program?

MDUFA

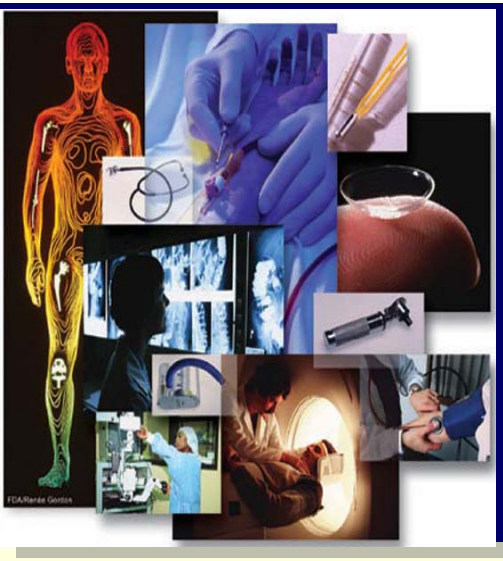
MDUFA Background

- 2002- Congress first granted FDA the authority to collect user fees from medical device establishments.
  - **2002** Medical Device User Fee and Modernization Act (MDUFMA)
  - Amended by the Medical Device Technical Corrections Act and the Medical Device User Fee Stabilization Act of **2005**
  - Reauthorized in the Medical Device User Fee Amendments of **2007** (MDUFA 2007), enacted as Title II of the Food and Drug Administration Amendments Act of 2007
  - 2007 amendments expire on October 1, 2012
- Goal- reduce review times
  - User fees establish/adjust FDA *performance goals*

SUMMARY

Three areas that will impact program

- Internal 510(k) Implementation Teams
  - Targeted completion- 2011
  - Additional opportunities
    - public meeting
    - comments
- IOM Report
  - Recommendations due this summer
  - Several FDA issues are referred (IIb, Off-label use, etc)
- MDUFA Negotiations ???



Thank You