Medical Device Regulation: A Delicate Balance, An Evolving Process
What does it mean to you?

Mass Medic
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Regulation: A Delicate Balance
Mandate to protect the public health

VS.

Patient autonomy

Product safety and effectiveness

VS.

Product availability
“Total Product Life Cycle” Vision

Efficient, Effective, and Predictable Product Development

Ensuring the Safety of Marketed Medical Devices

Enabling Access to Innovation
Change is Inevitable

- Temple report
- Reengineering
- Strategic Planning
- Post-market Transformation
- 510(k) Reform
- Innovation Initiative
• To what end?
• How much?
• How fast?
• What will it cost?
• What will it accomplish?
Technology Evolves

21 CFR 870.1875
Stethoscope

Pro Code: LDE
Manual Stethoscope
Class 1 510(k) Exempt

Pro Code: OCR
Lung Sound Monitor
Class 2 510(k) Required

Pro Code: DQD
Electronic Stethoscope
Class 2 510(k) Required
<table>
<thead>
<tr>
<th>Year</th>
<th>Legislative Mandate</th>
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<tbody>
<tr>
<td>1976</td>
<td>Medical Device Amendment of 1976</td>
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<tr>
<td>1988</td>
<td>Clinical Laboratory Improvement Amendments (CLIA)</td>
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<td>1990</td>
<td>Safe Medical Devices Act (SMDA)</td>
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<td>1992</td>
<td>Mammography Quality Standards Act (MQSA)</td>
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<td>Medical Device Amendments</td>
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<td>1997</td>
<td>Food &amp; Drug Administration Modernization Act (FDAMA)</td>
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<td>2002</td>
<td>Medical Device User Fee and Modernization Act (MDUFMA)</td>
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<tr>
<td>2005</td>
<td>Medical Device User Fee Stabilization Act (MDUFSA)</td>
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<tr>
<td>2007</td>
<td>Food and Drug Administration Amendments Act of 2007 (FDAAA)</td>
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<td>2012</td>
<td>FDA Safety and Innovation Act (FDASIA)</td>
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Leadership changes since 2009
FDA’s Two Pronged Approach to 510(k) Reform:

External Evaluation
Institute of Medicine (IOM) - independent evaluation of the 510(k) program

CDRH Evaluation
510(k) Working Group - evaluate how well the 510(k) program was meeting its two public health goals and explore actions CDRH should take to strengthen it
• **510(k) Internal Evaluations**

• **510(k) IOM Report**
  [http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx](http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx)

• **510(k) Science Report**

• **CDRH 510(k) Action Plan**
  [http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm)
“The term ‘substantially equivalent’ is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness.”

1976 Congressional Record
Investigational Device Exemption (IDE)

- A key piece of the R&D process
- For many devices, first contact with CDRH
- Patient must be protected, however
- Approvability cannot be guaranteed
- Timeliness and flexibility are essential
• Highest risk/reward

• Generally less certainty, more questions

• Benefit/Risk Guidance should help but,

• Cannot substitute for good judgment and,

• Appropriate pre/post-market balance
Patient Access to Medical Devices — A Comparison of U.S. and European Review Processes

Commissioner's Enforcement Initiative

- Enhanced regulatory oversight and timely Agency follow-up action including aggressive Enforcement Action, when appropriate
- Coordinated risk review regarding device performance
- Increased accountability to improve Warning Letter and recall processing times
- Additional inspection resources
Increased attention to compliance and enforcement at CDRH

- New Director of Compliance Office, Steve Silverman
- Enhanced screening of imports
- Global data sharing
- 3rd party (public and private) inspections and oversight
- Emphasis on business benefits to compliance
Innovation Pathway

Eligible Devices Must be Truly Pioneering Medical Devices and Meet One of the Following Criteria:

1. Significantly improve upon currently available treatments or diagnostics for life-threatening or irreversibly debilitating diseases or conditions;

2. Treat or diagnose a life-threatening or irreversibly debilitating disease or condition for which no approved or cleared alternative treatment or means of diagnosis exists;

3. Address an unmet public health need as identified by the Council on Medical Device Innovation; or

4. Address an issue relevant to national security
• From the outset, the goal has to provide patients with timely access to safe and effective products

• This requires enhancements to make the premarket process more predictable, transparent and efficient

• Important to note that the Commitment Letter states:

  “Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices.”
Resources

• $595 Million over 5 years (plus inflation)
  – MDUFA I-$142M over 5 years
  – MDUFA II-$287 million over 5 years

• Bulk of increase generated from lifting fee exemption on annual registrations

• FY13 submission rates lower than initial FY12 expectations

• Adjusted annually for actual inflation with 4% cap in any year

• Addition of 240 FTEs (32 new FTEs in FY12 from excess MDUFA II funds and 208 FTEs under MDUFA III)
### Comparison of MDUFA Goals

<table>
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<tr>
<th>Submission Type</th>
<th>MDUFA II Goal (FDA Days to MDUFA Decision)</th>
<th>MDUFA III Goal (FDA Days to MDUFA Decision)</th>
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</table>
| 510(k)                          | Tier 1: 90% in 90 days  
Tier 2: 98% in 150 days                                        | No tiers in MDUFA III (90 days)                               |
|                                 | FY 2013: 91%  
FY 2014: 93%  
FH 2015-17: 95%                                                   |                                                               |
| Original PMA & Panel Track      | Tier 1: 60% in 180 days  
Tier 2: 90% in 295 days                                        | No tiers in MDUFA III:                                        |
| Supplements                     |                                                               | Panel  
(320 days) |
|                                 |                                                               | No Panel  
(180 days) |
|                                 |                                                               | FY 2013: 50%  
FY 2014: 70%  
FY 2015: 80%  
FY 2016: 80%  
FY 2017: 90% |
| Expedited PMAs                  | Tier 1: 50% in 180 days  
Tier 2: 90% in 280 days                                        | Expedited PMA performance goals are included with “Original PMAs” |
| 180-Day PMA Supplements         | Tier 1: 85% in 180 days  
Tier 2: 95% in 210 days                                        | No tiers in MDUFA III (180 days)                              |
|                                 | FY 2013: 85%  
FY 2014-15: 90%  
FY 2016-17: 95%                                                   |                                                               |
For the first time, the MDUFA III Agreement creates a performance goal that tracks the total time elapsed during an FDA review.

Average total time to decision goals in calendar days

- **PMAs**
  - 395 calendar days for 2013 submissions
  - 390 calendar days for 2015 submissions
  - 385 calendar days for 2017 submissions

- **510(k)s**
  - 135 calendar days for 2013 submissions
  - 130 calendar days for 2015 submissions
  - 124 calendar days for 2017 submissions
Quarterly and annual reporting
  - Progress towards performance goals
  - Additional information
    • Average number of review cycles
    • NSE rates
    • Withdrawal rates
    • Not approvable rates
    • IDE information
    • AI information
  • Annual performance report to Congress
  • Independent evaluation of FDA’s management of review process
• Investigational Device Exemptions (IDEs)
  - Reaffirms FDA can not disapprove an IDE because it would not support marketing application but...

• 510(k) Modifications
  - Guidance withdrawn
  - FDA report to Congress
  - 1997 Guidance remains in effect

• Enhanced scientific rationale for major decisions and expedited appeals

• Eliminates profit prohibition for Humanitarian Device Exemptions (HDEs)

• De Novo Reform
  - Company can seek direct review without 510(k) Not Substantially Equivalent determination by FDA
Legislative Reforms

- Reclassification: Can change classification via administrative order vs. regulation
- Explicitly includes devices in FDA’s Sentinel Initiative
- Provides specific dates to begin Unique Device Identifier (UDI) roll out
- Reaffirms FDA’s Condition of Approval Authority
- Directs FDA to improve recall system
Process Improvements?

- Scientific and Regulatory Review Capacity - reduce the ratio of review staff to front line supervisors and hire additional experts

- Enhanced Training for FDA reviewers

- Pre-submissions - More structure and clarity to the process, including the establishment of meeting minutes

- Submission Acceptance Criteria - FDA will update list of objective requirements, including E-Copy
There is clearly a desire at FDA to demonstrate change.

The fallout from all of these initiatives even prior to formal adoption of new policies is profound.

Where these changes will ultimately net out?

Will that delicate balance be restored?

What will be the ultimate effect on public health?
What can you do?

- Understand the new reality
- Get involved in the process
- Choose projects carefully
- Watch for curveballs
- Utilize the global market
- Anticipate further changes

Don’t Give Up!
THANK YOU!