Recommendations for Changes to the 510(k) Program

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Mission and Goal

- **FDA’s Mission:**
  - To **Promote** and **Protect** the Public Health

- **Translated:**
  - To provide timely access to safe and effective devices while fostering innovation

- **The goal of the 510(k) and Science reports is to allow the FDA to achieve both goals through a strengthened program**
The U.S. Food and Drug Administration issued two comprehensive evaluations containing recommendations that address three key objectives of the agency’s public health mission as it relates to medical devices –

- foster device innovation,
- create a more predictable regulatory environment, and
- enhance device safety.

One report focuses on ways to strengthen and clarify the 510(k) program for medical devices.

The other evaluates CDRH’s use of science in decision-making, with an eye toward adapting to new scientific information, while maintaining regulatory predictability necessary for innovation.
Don’t panic!

Draft reports published: August 5, 2010
  o Comment Period closed: October 4, 2010

55 Recommendations from both reports

Center is currently prioritizing recommendations

After comments are evaluated, a determination will be made regarding which recommendations to implement and which should wait until after the IOM report

Recommendations will go through notice as comment as appropriate
Fostering Device Innovation

- The 510(k) report recommends major improvements to the regulatory pathway for lower-risk novel devices that cannot be cleared through 510(k) but which do not warrant the more rigorous premarket approval review applied to higher-risk devices. The report calls for major reforms in the implementation of this process—called the de novo classification process. The recommendations include streamlining the process and clarification of CDRH’s expectations for submissions that undergo this type of review.

- The science report recommends that CDRH make better use of scientific experts outside of the agency by developing a web-based network of external experts using social media technology. This network would help CDRH staff leverage outside knowledge without serving in an advisory capacity.
Notable Recommendations

Enhancing Regulatory Predictability

- Develop a guidance document defining a subset of moderate-risk (Class II) devices, called Class IIb, for which clinical or manufacturing data typically would be necessary to support a substantial equivalence determination. This guidance document would help clarify what information submitters should include in their 510(k) submissions so that they can plan accordingly. In addition, this would also help the center’s review staff obtain the type and level of evidence necessary to make well-supported decisions without as much need for time-consuming follow-up requests for information.

- The science report recommends use of a standardized “Notice to Industry” letter that would generally be issued as a "Level 1 - Immediately in Effect" guidance document to quickly communicate when CDRH has changed its premarket regulatory expectations due to scientific information that has emerged about a certain device type. CDRH currently communicates this kind of information through individual interactions during the review process, which can lead to delays. These letters would provide greater clarity to affected manufacturers, in a timelier manner, about CDRH’s expectations with respect to a particular group of devices.
Notable Recommendations

Improving Patient Safety

- Revise regulations to explicitly require 510(k) submitters to provide a summary of all scientific information known or that the submitter should reasonably know regarding the safety and effectiveness of the device under review. This is not required now for 510(k) submissions and, as a result, relevant information may not be included in an initial submission. This summary would help CDRH review staff to more efficiently make decisions, and potentially avoid extensive follow-up inquiries and questions.

- Develop a guidance document that clarifies when a device should not be used as a predicate, such as when the device has been removed from the market because of safety concerns. The report also recommends that the center consider issuing a regulation that would clarify the circumstances under which the center would exercise its authority to rescind a 510(k) clearance to remove an unsafe device from the market and preclude its use as a predicate and also consider whether additional authority is needed.

- Build upon public databases to include meaningful, up-to-date information that supports good decision making and promotes the safe use of devices. This could be accomplished by improving the current 510(k) database so that it includes summaries of FDA review decisions, current labeling and photos.
General Comments

- CDRH should not implement all recommendations at once
- Notice and comment should be allowed once detailed recommendations are developed
- Innovation should not be hindered by proposed changes
- 510(k) should be improved to provide greater consumer protection
Recommendations with strong support

- Revise the de novo process
- Improve the guidance process
- Issue guidance in a number of areas
  - Clarify technological characteristics
  - Clarify the difference between intended use and indications for use
- Training
- Access to external expertise and establish a science counsel
Recommendations with mixed support

- **Periodic reports**
- **Class IIb**
  - Initial comments before the report issued supported concept
  - Comments now are less supportive
- **Rescission**
  - Industry comments are not supportive, or are supportive only in cases of fraud
  - Other stakeholders are supportive
- **Predicates**
  - Guidance on use of predicates ✓
  - Restrictions on split predicates ❌
Recommendations with significant concern

- Posting pictures or schematics of the device
- Combining Intended Use and Indications for Use
  - Clarify but don’t combine
  - “fear” that products must be identical
- **Statutory authority for off-label use**
- **Manufacturing information/pre-clearance inspections**
The recommendation on rescission is **not** intended to add any authorities over what the agency believes are currently existing. **It is intended to provide transparency and predictability by:**

- assuring the 510(k) holder due process rights;
- providing the 510(k) holder an opportunity for an informal hearing before issuing a rescission order; and
- issuing a regulation providing the 510(k) holder with the opportunity to request a hearing to challenge a proposed withdrawal.
The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence. (intended use and technology)

2. Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

3. (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or

(ii) a court has issued a judicial order determining the legally marketed device(s), on which the substantial equivalence determination was based, to be misbranded or adulterated.
4. The premarket notification contained or was accompanied by an untrue statement of material fact.

5. The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable Institutional Review Board regulations (21 CFR part 56) or informed consent regulations (21 CFR part 50) in a way that the rights or safety of human subjects were not adequately protected.

6. The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under 21 CFR 812.119.

As proposed, these would be bases to rescind because information in the 510(k) is incorrect, incomplete, unreliable, or not evaluated properly by FDA in accordance with section 513(f) and (i) of the act.
Class IIb

- **Intended to provide predictability**
  - Identify data needs based on **existing** review requirements

- **Intended to be fluid**
  - Devices could move off of the list

- **Provide a level of harmonization**

- **Intended to apply to the broad category of existing Class II devices**
Comments are mixed:

- Some disagree due to burden

- Some think it should be applied to certain devices types

- Some are supportive and feel that FDA reviewers should not have to play Where’s Waldo
Multiple Predicates

New Device

Predicates
Multiple Predicates

**New Device**

sizes 3.0 – 10.00 mm

**Predicates**

Sizes 3.0 – 6.0 mm

Sizes 6.0 mm – 10.0 mm
### Multiple Predicates

**New Device**

- **Annuloplasty Ring**
  - Design X
  - Material Y

**Predicates**

- **Annuloplasty Ring**
  - Design X
  - Material X

- **Annuloplasty Ring**
  - Design Y
  - Material Y

Center for Devices and Radiological Health
Split Predicates

- **New Device**
  - Low Energy Ultrasound Wound Cleaner

- **Most Appropriate Pathway**
  **De Novo**
  - Based on well understood technology it is possible to write special controls to support a Class II classification

- **Predicate Devices**
  - Wound Flush Solution
    - Class II
      - Intended Use
  - Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions
    - Class II
      - Technology
The committee will assess whether the 510(k) clearance process sufficiently protects patients and promotes public health. Specifically, the IOM committee will answer two principal questions:

- Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
- If not, what legislative, regulatory, or administrative changes are recommended to optimally achieve the goals of the 510(k) process?

A report is expected in mid-2011.
Meeting 1: March 1, 2010
- 510(k) History and Current Process

Meeting 2: June 14-15, 2010
- Legislative History, Compliance, Harmonization, Innovation

Meeting 3: July 28, 2010
- Postmarket Surveillance

Report with recommendations expected Mid-2011

Presentations are available on IOM website
Thank You

Questions?

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