



A Closer Look at 510(k) Changes with AdvaMed's Janet Trunzo

Friday, February 18, 10:00am

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Answers before Questions

- Slides available by request
 - *Email Matt at mschutte@bioohio.com*
- Recorded version of this webinar available on BioOhio.com for BioOhio members; registrants will receive link...
 - if moderator remembers to hit “record”*

Today's Agenda

- Welcome and Intro
 - Matt Schutte, BioOhio Director of Corporate Communications
- Analysis of CDRH 510(k) plan of action
 - Janet Trunzo
Executive V.P., Technology and Regulatory Affairs
- Q&A
 - *Raise your “virtual hand” at any time to ask question “on air” if you are using “telephone” audio, or submit question on bottom of webinar dashboard for moderator to read*



AdvaMed

Advanced Medical Technology Association

A Closer Look at 510(k) Program Changes

Janet Trunzo

Executive Vice President

Technology and Regulatory Affairs

BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

February 25, 2011

About AdvaMed



- World's largest medical technology association supporting device and diagnostic manufacturers
- More than 400 member companies and an additional 500 distinct subsidiaries and divisions.



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- More than 70% of member companies have less than \$30 million in annual revenue
 - Smallest manufactures can join for \$299



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- 68 staff with bi-partisan backgrounds
 - Areas of expertise include technology & regulatory affairs, reimbursement, legal/compliance and international
 - 45 member Board of Directors including five from smaller companies – 18 member Board of Directors for separate AdvaMedDx

- FDA's 510(k) and Science in Regulatory Decisions Report
- Result of FDA's internal evaluation
- Implementation for recommendations issued last August
- IOM study of 510(k) program due this summer

- 31 separate actions for 2011
- 7 recommendations referred to IOM
- 4 recommendations—case by case guidance

- Incorporated many AdvaMed comments
- Scaled back several recommendations
- More balanced approach
- Opportunity for further comments
- Details in guidance document/proposed rules key to implementation

- Draft guidance document development
- Proposed rulemaking
- Internal FDA procedures (SOPs, training)
- Pilot program
- Public meetings
- Referral to IOM

Key Recommendations with General Support

- Enhanced reviewer training
- Streamlining *de novo* process
 - Draft guidance
- Leveraging external experts
 - SOP
- Establishing Center Science Council for oversight/consistency in review decisions
 - Council charter on FDA website

Key Recommendations with FDA's Proposed Action

- Consolidation of “intended use” with “indications for use”
 - Referred to IOM
- Limitations on use of multiple predicates
 - No limitation
 - Strong support for use of multiple predicates
 - Guidance clarifying appropriate use
- Disallowing use of split predicates
 - Different meaning to different groups
 - No longer use term

Key Recommendations with FDA's Proposed Action

- Consideration of off-label use during 510(k) review
 - Referred to IOM
- Clarify when device is no longer available as predicate
 - Referred to IOM
- Establishment of Class IIb
 - Referred to IOM

Key Recommendations with FDA's Proposed Action

- Clinical information in 510(k) submission
 - Guidance on when clinical data should be submitted
- Expansion of rescission authority
 - Referred to IOM
- Manufacturing information in 510(k) submissions
 - Device-specific guidance
 - Types of manufacturing information needed to address relevant issues

Key Recommendations with FDA's Proposed Action

- Submission of periodic reports updating changes
 - Device-specific guidance
- Conditions of clearance studies
 - Referred to IOM
- Pre-clearance inspections
 - Device-specific guidance
- Release detailed photos and schematics in public database
 - FDA to hold a public meeting

Key Recommendations with FDA's Proposed Action

- Labeling available in a public database
 - Potential link to manufacturers database
 - Public meeting
- Summary of all available scientific information in submissions
 - Elimination of “reasonably known”
 - Device specific guidance
 - Summary information only

Key Recommendations with FDA's Proposed Action

- Assurance case framework applicable to all 510(k)s
 - Pilot study on infusion pumps
 - Analyze pilot and decide next steps
- Maintaining a unit of device to give to FDA
 - Recognized burden on industry
 - Referred to IOM
- Limitation on use of consensus standards
 - Guidance clarifying appropriate use of standards

Key Recommendations with FDA's Proposed Action

- Limitation on use of third party reviews
 - Enhance third party reviewer training
 - Identify eligible device types
- Revision of least burdensome guidance document
 - No revision of current guidance
 - Training of reviewers on current guidance

Key Recommendations With FDA's Proposed Action

- Notice to Industry letters
 - SOP for clarifying parameters for issuing letters
- IDE Process improvements
 - Analysis of IDE program
- UDI system
 - UDI regulation by June 2011



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