


Changes in FDA for 2012

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Changes in 510(k) Clearance Program

- Changes in FDA
 - New Staff
 - Outside pressure to make device clearance more rigorous
 - Result: Bar has been raised for clearing products with innovation
 - 10% of all 510(k)s require clinical data for success.
- Changes result in need for a more rigorous risk management approach



Risk Focused FDA Guidance Documents

- August 2011: FDA Draft Guidance – Factors to consider when making Benefit-Risk determinations in medical device premarket review
- July 2011: FDA Draft Guidance - 510(k) device modifications
- June 2011: Human factors and Usability Engineering to Optimize Medical Device Design
- Dec 2012: The 510(k) program – Evaluating SE



Hot Topic from the Trenches

How is the changing landscape of FDA
changing the likelihood for success in
obtaining product clearance?





Selling Medical Devices in USA

- How it has always been: Before a manufacturer can enter into interstate commerce with a device, the class of the device should be identified and acted on appropriately
 - General Controls apply to all classes
 - Registration
 - Device Listing
 - GMP
 - Prohibitions on adulteration or misbranding
 - May include Premarket Notification 510(k)
- Class defines the level of regulatory control necessary to provide a reasonable assurance level of safety and efficacy.



Device Class

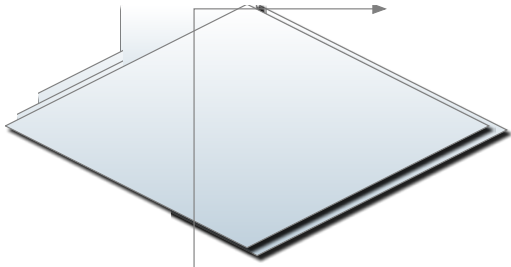
- Class I
 - General Controls
- Class II
 - General Controls
 - Added special controls
 - Performance Standards
 - Post market surveillance
 - Patient registry
 - Guidance documents
- Class III
 - General Controls
 - Special controls are insufficient to provide assurance of safety and efficacy
 - Usually require PMA



Overview of Draft Guidance

So what is different now?

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Making the Case of SE

- Identify a predicate
- New device
 - Same class as predicate
 - Subject to same requirements as predicate
- Critical: Does new device evaluation support the conclusion that there are no new risks and no decrease in device efficacy?

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Areas of Higher Risk

- Technology changes
- Manufacturing changes (ex: nanofabrication)
- Change in surgical techniques

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Use of Multiple Predicates

- Route 1 – Same intended use
 - When multiple predicates are used to treat multiple diseases or symptoms that fall into same intended use.
 - Intended use is fracture fixation but in various areas. Therefore, separate indications but same intended use
- Route 2 – Multiple technologies in one device
 - Example: Urinary catheter that measures temperature
- Route 3 – Reference devices (most complicated)
 - Example: Knee implant with coating X not used in knees, but hip implant has coating X. Hip implant can be used to show biocompatibility is not altered in knee device.



NSE Decision: Really Class III or Simply Incomplete 510(k)?

- FDA's determination that the device is a Class III and cannot be reviewed in the 510(k) process
 - Lack of predicate, new intended use, or technology change that raise a new issue of safety or efficacy
 - Usually NSE Letter will not identify performance based deficiencies
 - If you have any doubt as to your product classification / product code, query FDA via a 513(g) submission
 - Automatic Class III designation or De Novo (FDA will usually indicate if De Novo is suggested)

- Inadequacies in the evidence presented
 - Information provided is insufficient to prove SE
 - FDA will identify need for additional information
 - Once questions are answered, sponsor can submit new 510(k)



Summary of Draft Guidance

- 510(k) summaries must be more transparent
- FDA is clearly stating that risk identification and management is critical in the route to SE
- Less liberal use of multiple predicates
- Good scientific data supporting safety and efficacy as compared to predicate

First step to creating the case for substantial equivalence is a rigorous risk management program...



Are you doing a good job
evaluating risk?

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Critical Areas of Risk Analysis

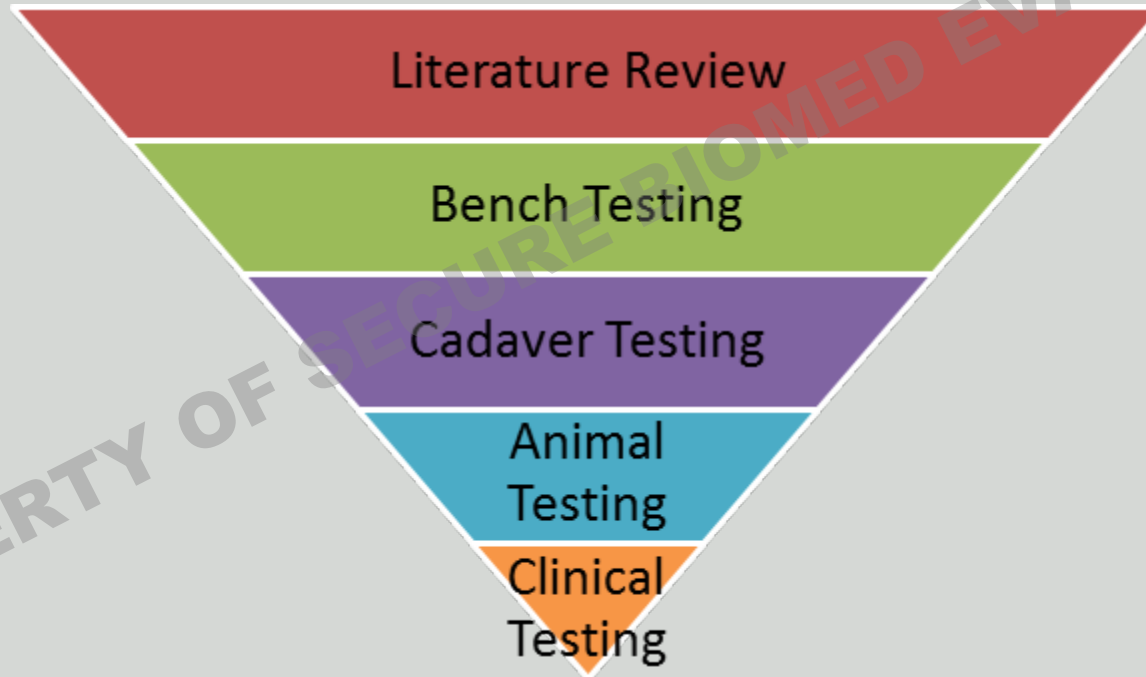
- Design
- Process
- Usability

- Steps
 - Identify Risks
 - Evaluate and / or Test Severity
 - Mitigate or Control
 - Re-evaluation (this part never ends)



Risk Evaluation

RISKS



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Risk Identification Process

- Define intended use
- Define FDA product code
- Identify predicates
- Understand what FDA considers to be the normal device risks
 - TPLC Search
 - Perform clinical evaluation – literature review portion
- Define physiological setting (loads, etc...)
- Define the risks for the device

Bench, animal, cadaver and clinical studies should be in response to the need for evaluating the risk of a device...



Does the testing properly evaluate risk?

- Be brutal in your analysis
- If you have doubts assume FDA will come back with an NSE
- Can you really evaluate your device risks without clinical data?
- Biggest mistake – Not addressing differences between new device and predicate. Does a difference create a new risk?
 - Design review needs to have an outside evaluator



Latest Trend from FDA - Usability

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Clinical Usability Studies

- Study Plan
 - Exploratory with engineers (n=5)
 - Assessment with clinicians (n=5)
 - Validation with clinicians (n=15)
- Considerations
 - Is it important to consider all clinician users with different skill level – surgeon, physician, nurses, PA
 - Evaluate intended patient population



Human Factors / Usability Success

- Focus on identifying errors
- Test high risk tasks
- Test appropriate user population (may be multiple skill levels)
- Document risks and then make changes (design, IFU, etc...)

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Tips and Tricks from the Trenches

- Do you need clinical data to show SE?
 - Literature Review
 - Patient Study
- If you need a usability study, don't wait for FDA to ask.
 - Top level physicians are excellent for the clinician assessment but validation studies should be done with all levels of users, not just the best.
- If your independent reviewer identifies a new risk, be careful about simply dismissing.
- If you are doing an animal study, don't waste money on a non-GLP study



Take Home Message

“Changes” in FDA are more about having consistent, reproducible documentation to ensure safe and effective devices.

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