

Developing a Risk Profile for Medical Devices:

The Role of Clinical Evaluations and Risk Assessments

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Risk Based Approach to Device Clearance

- FDA
 - Safe
 - Effective
- CE Marking
 - Safe

Critical New Product Question:

- Does the device / design / manufacturing process / usability raise a new type of safety or effectiveness concern?





FDA Trends in Risk Management

- August 2011: FDA Draft Guidance – Factors to consider when making Benefit-Risk determinations in medical device premarket review
- July 2011: FDA Draft Guidance - 510(k) device modifications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



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)



Best Practices in Risk Management

Clinical Evaluation

ID Risks

Risk Assessment

Determine
unacceptable risk

Non-Clinical Test Design

Use data from CE
and RA to design test
matrix



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Risk Identification Process

- Define intended use
- Define FDA product code
- Identify predicates
- Perform clinical evaluation – literature review portion
- Define physiological setting (loads, etc...)
- Define the risks for the device

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



Step 1: Risk Identification

Data Sources

- Published Literature
- FDA Website
 - Guidance Documents
 - TPLC Database
 - MAUDE reports
 - Recalls

Methodology

- Clinical Risk Benefit Analysis
 - MDD 93/42/EEC: Check list states a clinical evaluation must be performed for each product or family of products.
 - MEDDEV 2.7.1 Rev 3: Guidance for manufacturers and notified body



TPLC Database: Gifts from FDA!

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Device	Screw, Fixation, Bone
Regulation Description	Smooth or threaded metallic bone fixation fastener.
Regulation Medical Specialty	Orthopedic
Review Panel	Orthopedic
Product Code	HWC
Submission Type	510(k)
Regulation Number	888.3040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Recognized Consensus Standards	
<ul style="list-style-type: none">• ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components• ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments• ASTM F 897-02 (Reapproved 2007) Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws• ASTM F 2026-08 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	
Third Party Review	Not Third Party Eligible



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TPLC

Device Problems	
<u>Unknown (for use when the device problem is not known)</u>	402
<u>Implant, removal of</u>	203
<u>Break</u>	129
<u>Fracture</u>	79
<u>No Known Device Problem</u>	61
<u>Device, or device fragments remain in patient</u>	44
<u>Device remains implanted</u>	40
<u>No Information</u>	40
<u>Other (for use when an appropriate device code cannot be identified)</u>	38
<u>Device Issue</u>	36
<u>Component(s), broken</u>	33
<u>Loose</u>	33
<u>Electro-magnetic interference (EMI)</u>	30
<u>Malfunction</u>	26
<u>Migration of device or device component</u>	25
<u>Implant breakage or physical damage</u>	20
<u>Displacement</u>	19



Step 2: Evaluate (ISO 14971)

- Risk Management Areas: May be found as part of the clinical risk benefit analysis or as a potential new risk of a design change.
 - Design
 - Process
 - Usability
- Methodology: Up to company to determine how best to analyze risk.
 - Hazard Analysis
 - FMEA
 - Fault Tree
 - Etc...





Step 3: Testing the Risk

- Mechanical test design
 - Level 1: Guidance document
 - Level 2: Testing called out in clinical evaluation review
 - Level 3: Design of novel tests to evaluate a device risk

- Process
 - Determine test matrix
 - Define acceptance criteria before testing
 - For regulatory submissions, know the answer before you start





Step 4: Preparing Regulatory Submissions

- Substantial equivalence argument
 - Table comparing all aspects of the device
 - Need:
 - Predicate performance and safety data
 - Published in literature
 - Side by side analysis
- 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



Step 5: Post Market Surveillance

- Risk management through lifecycle of product
- Post Market Data Sources
 - Data from your product
 - Data from competitor's product
 - Trends in industry





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





FDA Rejections based on Human Factors

- Test procedures missing
- Insufficient user error analysis and mitigation
- Inappropriate failure acceptance (failures should not be accepted but instead mitigated)
- Not using a realistic simulated setting (lab versus physician's office)
- Insufficient user performance criteria (how do you know what it is done correctly or incorrectly?)
- Unrealistic training (must match actual training in the field)





Steps to HFE Success

- **Prepare for validation success.**
 - Systematic user interface testing and analysis during early design stages should reduce and eliminate use error risks to acceptable levels, so that validation reveals few if any problems.
- **Focus on use error identification, not measuring task success/failures.**
 - Tests with 15 or more users should enable identification of remaining use errors in user-device interactions. Determine and clarify use error root causes in post-test interviews. Explain why the current design cannot be reasonably modified to reduce a use hazard or how warning methods will communicate the risks.
- **Test high-risk tasks.**
 - Testing should include the device interaction sequences that represent high risk to patient or user safety as identified in analysis and testing in early phases.
- **Test appropriate user populations.**
 - Enlist participants from the user population that reflect the expected education, experience, training, and skill sets. Participants should not be current employees of the manufacturer.
- **Describe and test mitigations.**
 - Further testing focusing specifically on proposed use hazard mitigations is warranted as evidence of their effectiveness.





Tips and Tricks from the Trenches

- Do not underestimate the time needed to do a thorough clinical evaluation / clinical risk benefit analysis.
- Always summarize findings in a “Conclusions” type document.
- Make sure identified risks from clinical evaluation make it to your company’s risks evaluation process.
- Using design to mitigate a risk is always superior to packaging / labeling measures.
- If you need a usability study, don’t wait for FDA to ask.

