Orthopaedic SMART Devices Workshop:
Orthopaedic SMART Device Evaluation
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Orthopaedic SMART Devices Overview

- Verification and validation activities
- Risk based concepts
- Theoretical example to illustrate risk based concepts
- Discussion points to consider
Verification and Validation: Considerations for orthopaedic implants

• Mechanical Testing - multiple FDA guidance documents and applicable ASTM and ISO standards

ISO 7206-4

ASTM F1717-15
Verification and Validation: Considerations for orthopaedic implants

Biocompatibility

• **FDA guidance:** *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

• **ISO 10993-1:** *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

http://www.cytox.de/en/services/cytotoxicity-test/
Verification and Validation: Considerations for orthopaedic implants

Software

• **FDA guidance: ** *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*

• **FDA guidance: ** *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*

• **ISO 14971: ** *Medical devices – Application of risk management to medical devices*
Verification and Validation: Considerations for orthopaedic implants

EMC

- FDA guidance: *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices*

Verification and Validation: Considerations for orthopaedic implants

Usability

- FDA guidance: Applying Human Factors and Usability Engineering to Medical Devices
- Applicable consensus standards (Appendix D of FDA guidance above)

www.fda.gov
Verification and Validation: Considerations for orthopaedic implants

Labeling

- Follow FDA Regulations – 21 CFR 801

- Guidance: *Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*
  [https://imgur.com/gallery/699Vc](https://imgur.com/gallery/699Vc)
Verification and Validation:
Potential considerations for sensor data

Analytical Validation:
• Repeatability
• Reproducibility
• Limit of Detection
• Interference
• Linearity
• And Others

CardioMEMS HF System
P100045 (Approved 5/28/2014)

Table 1. Summary of Testing- Sensor, Delivery System, and Electronics

<table>
<thead>
<tr>
<th>Sensor Functional Testing</th>
<th>Acceptance Criteria</th>
<th>Results</th>
<th>Analysis Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor Accuracy</td>
<td>Sensor must measure within ± 2 mmHg at baseline and ± 3% across the pressure range compared to a reference pressure measurement for a pressure range of 600-860 mm Hg (absolute).</td>
<td>Pass</td>
<td>Variable</td>
</tr>
<tr>
<td>Simulated Use Pressure Cycle Conditions</td>
<td>Sensor must continue to function throughout 10 years of simulated fatigue testing (400 million cycles).</td>
<td>Pass</td>
<td>Attribute</td>
</tr>
<tr>
<td>Sensor Detection Distance</td>
<td>Sensor must be detectable by the external measurement system at &gt; 4” and &gt; 50% signal strength in physiological saline.</td>
<td>Pass</td>
<td>Variable</td>
</tr>
<tr>
<td>Temperature Sensitivity</td>
<td>Sensor pressure measurement change per unit temperature change: +1 ± 1mm Hg / °C.</td>
<td>Pass</td>
<td>Variable</td>
</tr>
<tr>
<td>Over-Pressure Exposure</td>
<td>Sensor must meet functional requirements after exposure to 2.0 atm.</td>
<td>Pass</td>
<td>Attribute</td>
</tr>
<tr>
<td>Mechanical Shock</td>
<td>Sensor must meet functional requirements after shock and vibration testing, per ISTA-2A.</td>
<td>Pass</td>
<td>Attribute</td>
</tr>
<tr>
<td>Corrosion</td>
<td>Metallic components shall show no sign of corrosion in testing per ISO 14708-1, part 23.1.</td>
<td>Pass</td>
<td>Attribute</td>
</tr>
<tr>
<td>Sensor Radiopacity</td>
<td>Catheter shaft is visible under fluoroscopy.</td>
<td>Pass</td>
<td>Attribute</td>
</tr>
</tbody>
</table>

P100045 Summary of Safety and Effectiveness Data:
https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045
B.pdf
Risk Based Concepts:
Potential considerations for sensor data interpretation

• What type of data are being produced?

• How are the data being interpreted and utilized?

• How does collection and interpretation of data ultimately affect the risk?
Risk Based Concepts:
Clinical Association of Output Data

Is the clinical association well understood by the intended user, established, and publicly available (e.g., clinical practice guidelines, published literature) or is it a novel clinical association?
Risk Based Concepts: Data Interpretation

How is the output information intended to be used?

1. As an adjunct to established treatment algorithm;

2. As a replacement of a portion of the treatment algorithm; or

3. As a new treatment algorithm
Risk Based Concepts:
Patient condition

• Is the treated condition or targeted situation critical or non-critical?
Theoretical example to illustrate concepts

The concept of measuring strain on fixation devices is not novel.

Theoretical Scenario 1: Adjunctive data with no strain numbers, criteria for interpretation, or reference values in the labeling.

How does the information output change the benefit/risk?
**Theoretical Scenario 2:** Adjunctive data with strain numbers, criteria for interpretation, and reference values in the labeling.

How does the information output change the benefit/risk?
**Theoretical Scenario 3:** Diagnostic capabilities replacing existing diagnostic tools.

How does the information output change the benefit/risk?
Theoretical Scenario 4: Diagnostic and therapeutic capabilities replacing existing diagnostic tools and therapies in current treatment algorithms.

How does the information output change the benefit/risk?
SMART/sensor technology in the orthopedic space is new to the Agency. As part of a collaborative effort to develop a streamlined regulatory process, we hope that you consider the following questions for discussion:

• Does the output have **clinical meaning that is well understood** by the intended user, publicly available, and accepted by the clinical community?

• How does providing **adjunctive** information to the clinical treatment algorithm vs. **replacing** part of the clinical treatment algorithm change the benefit/risk profile?

• How does the **Benefit/Risk** evaluation change as the capability of the technology starts with monitoring and evolves to diagnostics and active treatment?

• Does **increasing influence** of sensor output data on clinical decision making affect benefit/risk and therefore the level of verification and validation necessary?
Points to Consider

How information is communicated to users and patients is important.

– The communicated intended use of a sensor’s output data should undergo benefit/risk analyses and, if necessary, appropriate risk mitigation activities

– Patient labeling should be considered to appropriately communicate the benefits and risks of the product to the patient

– As technologies and capabilities evolve and new output measures are validated, changes to device labeling should be considered to communicate appropriate updated information to users and patients
Thank You

If you have any specific questions about a certain device, (e.g., what types of changes require a new submission?), please submit a Q-Submission and/or contact the appropriate branch within the Division of Orthopedic Devices.