



Additive Manufacturing of Medical Devices: Software Documentation Considerations for Patient Matched Guides

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Overview

- Orthopedic Patient Matched Guides
- Patient Matched Guides and Software
- Existing FDA Software Guidance
- Approaches to Software Documentation



Orthopedic Patient Matched Guides

Orthopedic Patient Matched Guides

- Considered as accessories to an existing, orthopedic implant system.
- Implements the implant system's range of recommended alignments.
- Indicated to assist in the positioning of implanted orthopedic devices intra-operatively where anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans



Patient Matched Guides and Software



Patient Matched Guides and Software

Generic Design Process:

1. Patient image acquisition,
2. Image quality control and Segmentation,
3. Patient modeling and Anatomical definitions,
4. Pre-operative planning and Surgeon Approval,
5. Guide design and Patient matched feature definition, and
6. Guide construction.



Existing Software Guidance



Existing Software Guidance

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices (September 9, 1999)



Approaches to Software Documentation



Approaches to Software Documentation

Proprietary Software –

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Off-the-Shelf (OTS) Software – Basic Documentation

- What is it?
- What are the Computer System Specifications for the OTS Software?
- How will you assure appropriate actions are taken by the End User?
- What does the OTS Software do?
- How do you know it works?
 - 510(k) Cleared, Device Master File, Black Box Testing
- How will you keep track of (control) the OTS Software?



Thank you for your attention

Questions?