U.S. FOOD & DRUG ADMINISTRATION

Technical Considerations for Additive Manufactured Devices

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Joint Meeting on 3D Printed Patient-Specific Anatomic Models

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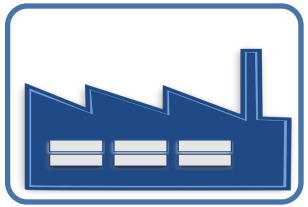
In Scope for the Guidance

Design Considerations

- Patient matching and complex geometries



Manufacturing Considerations

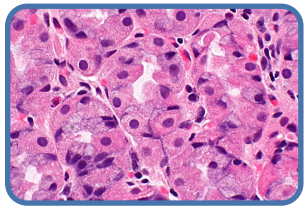
- QS requirements

Device Testing Considerations

- AM-specific data for a premarket submission

Out of Scope for the Guidance

Regulatory Policy



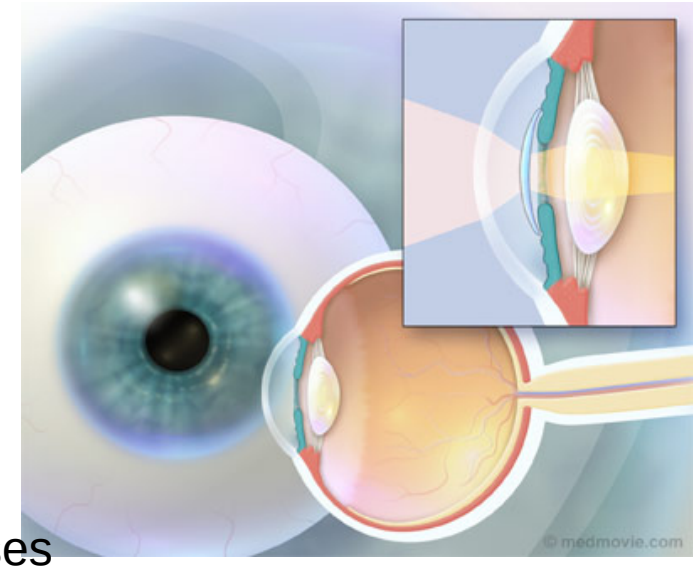
Cell / Tissue Printing

Specific device questions

- Address through pre-submission process

Important Note

FDA does not approve or clear materials for general* medical use



*Some dental materials are cleared for specific uses

DESIGN AND MANUFACTURING CONSIDERATIONS

Device Design

Motivation:

- Complex and patient matched designs.
- Features can be finer that technology allows

Technical Consideration:

- Machine's capabilities v. key design elements
- Quality of initial scan data
- Design criteria

Software Workflow

Motivation:

- Many file formats and conversions
- Human-in-the-loop.

Technical Consideration:

- Analyze processes and workflow for effects on AM.
- How does variability affect the final product

Material Controls

Motivation:

- Final material is produced *in situ*.
- Each technology, process, and use may have different material requirements.
- Starting material can be reused

Technical Consideration:

- Validate your material and/or re-use mixture for appropriate properties

Post-Processing

Motivation:

- Post-print processing can affect final performance

Technical Consideration:

- Describe any post-processing steps,
- Identify detrimental effects and mitigations

Process Validation & Acceptance

Motivation:

- Many settings / parameters can affect AM processes
- Generally less experience in controlling AM processes

Technical Consideration:

- Evaluate interrelationships between process steps
- Process monitoring techniques, and acceptance testing criteria may differ from other manufacturing techniques.

DEVICE TESTING CONSIDERATIONS

Performance Testing

Motivation:

- Build parameters (e.g. orientation, location) can affect final device

Technical Consideration:

- Factor in relevant parameters for worst-case
- Validation can leverage coupons and other methods

Material Characterization

Motivation:

- Starting material is altered to create final material.

Technical Considerations:

- Understand the effect printing on your material
- Additional considerations for resorbable or other active materials

Cleaning and Sterilization

Motivation:

- Various cleaning and support removal processes
  Complex geometries can make cleaning a challenge

Technical consideration:

- Validate to ensure manufacturing material is removed
- Include worst case geometries

Additional Labeling Considerations

Motivation:

- Patient matched devices may not always be identifiable by clinician

Technical Consideration:

- Label with patient identifier, location identifier, and design iteration.

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Thank you

FDA 3D printing website:

www.fda.gov/3dprinting/

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