FDA's Perspective on 3D Printing of Medical Devices

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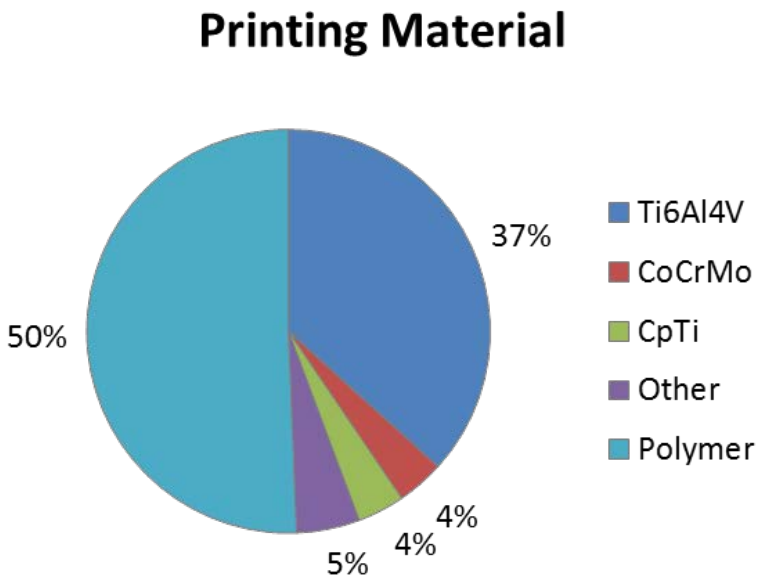
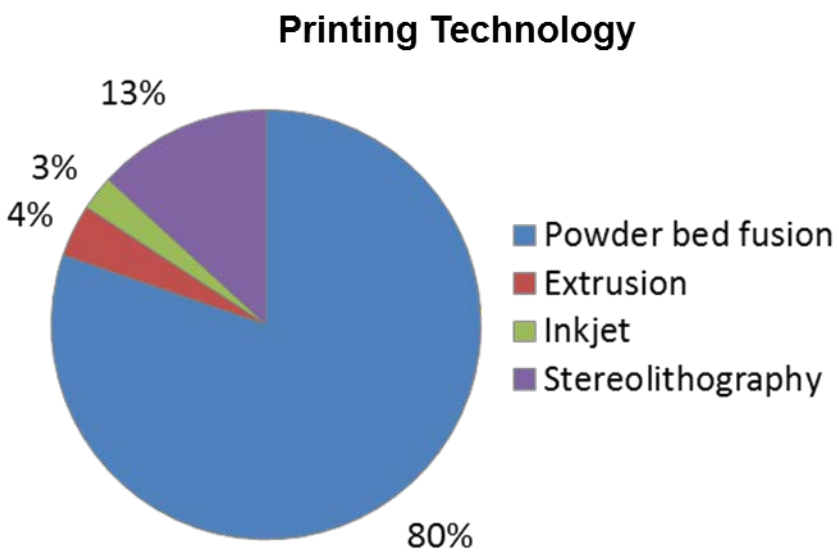
Overview of CDRH's AM Experience

- Regulated devices have been additively manufactured for more than a decade
- AM devices have been regulated through the same pathways as non-AM printed devices
- 70+ AM Devices cleared through the 510(k) pathway
- Majority of 510(k) clearances for orthopedic applications
- There have been some "emergency use" of AM devices
- First 3D printed drug approved in August (Spritam) via CDER

Overview of AM materials and technologies





Laura Ricles et al, 2015

Types of 510(k) Cleared AM Devices

- Patient matched implants
  - Skull plate
  - Maxillofacial implants

K121818
OsteoFab by OPM
http://www.accessdata.fda.gov/cdrh_docs/pdf12/K121818.pdf

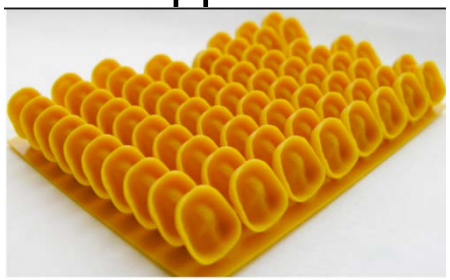
- Patient matched surgical guides
  - Craniofacial
  - Knee
  - Ankle

K120956
VSP® by Medical Modeling
http://www.accessdata.fda.gov/cdrh_docs/pdf12/K120956.pdf

- Orthopedic devices
  - Hip Cups
  - Spinal Cages
  - Knee trays

K102975
Novation Crown by Exatech
http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102975.pdf

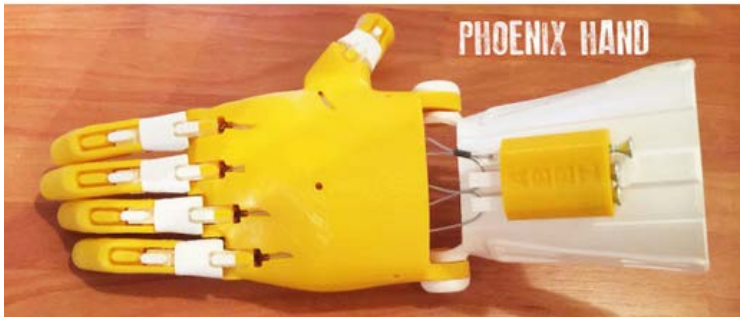
- Dental
  - Temporary bridges
  - Reconstructive surgery support



K102776
e-DENT Temporary Resin by DeltaMed GmbH
http://www.accessdata.fda.gov/cdrh_docs/pdf10/K102776.pdf

Other polymer based medical applications

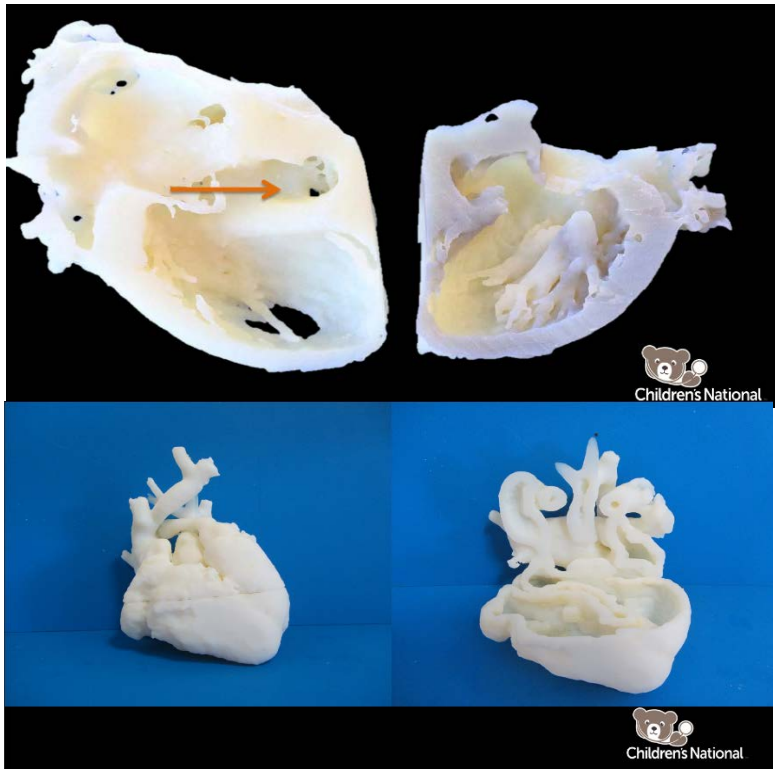
Unpowered prosthetics



http://enablingthefuture.org/upper-limb-prosthetics/

http://www.3ders.org/articles/20150604-lightweight-kafo-splint-3d-printed-leg-brace-cost-effectively-customized-for-perfect-fit.html

Patient models



http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM418406.pdf

Technical Considerations for Additive Manufactured Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on May 10, 2016.

TECHNICAL CONSIDERATIONS FOR ADDITIVE MANUFACTURED DEVICES

Draft Guidance

- Presents FDA's initial thoughts for comment by the public
- 90 day comment period, closes August 8
- When finalized, guidance represents agency's current thinking

- Draft guidance addresses both Manufacturing and Design Considerations as well as Device Testing Considerations

https://www.regulations.gov/#!documentDetail;D=FDA-2016-D-1210-0001 or search FDA docket draft guidance additive manufacturing

Manufacturing and Design

- Device Design
  - Separate concerns for standard and patient matched designs
- Software Workflow
  - Concerns ensuring proper file conversion and software interactions
  - Slicing, support, and build pathing could all affect final device performance

Manufacturing and Design

- Materials Control
  - Starting material should be fully characterized (including processing aids)
  - Material recycling protocol should be validated
- Post-processing
  - Post processing can have a significant impact on device performance

Manufacturing and Design

- Process Validation and Acceptance
  - Validation is a key component when full verification testing can not be performed
  - Revalidation can be needed when there is a change in the process
- Quality Data
  - Validation activities and design specifications will determine what data needs to be retained

Device Testing

- Device Description
  - Type of AM technology used and manufacturing workflow/post processing expected
- Mechanical Testing
  - Worst case consideration should include orientation and build location
- Material Characterization
  - Looking to characterize the material in the final device
  - Understand if there are any adverse material effects from the AM process

Manufacturing and Design

- Cleaning and Sterilization
  - Complex structures and channels could lead to challenges in cleaning (both manufacturing and reprocessing)
- Biocompatibility
  - Follow existing standards
- Additional Labeling Considerations (Patient Matched)
  - Revision of design
  - Anatomical descriptor
  - Patient identifier

Thank you!

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