3D Printing:
What we know and what we don't

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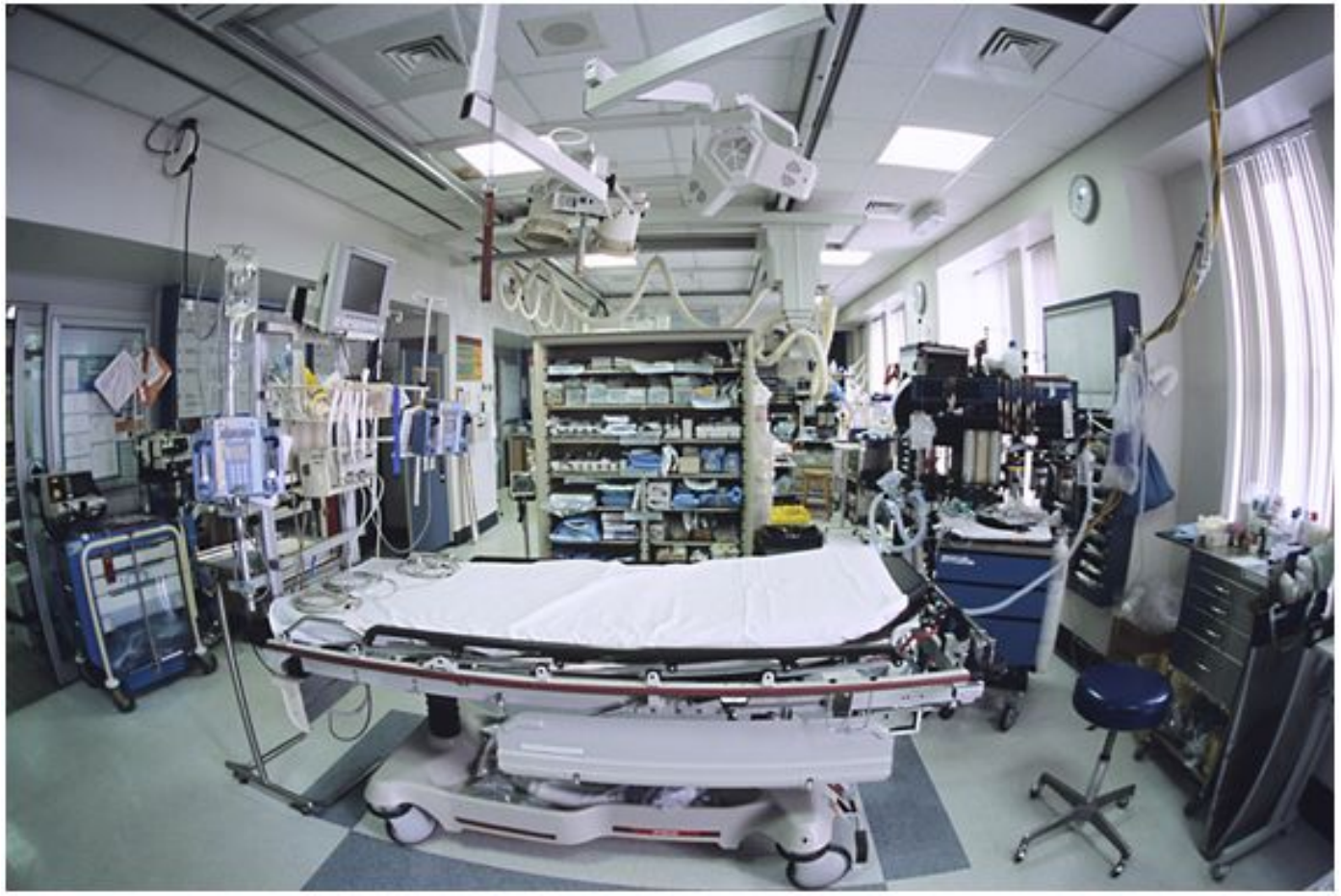
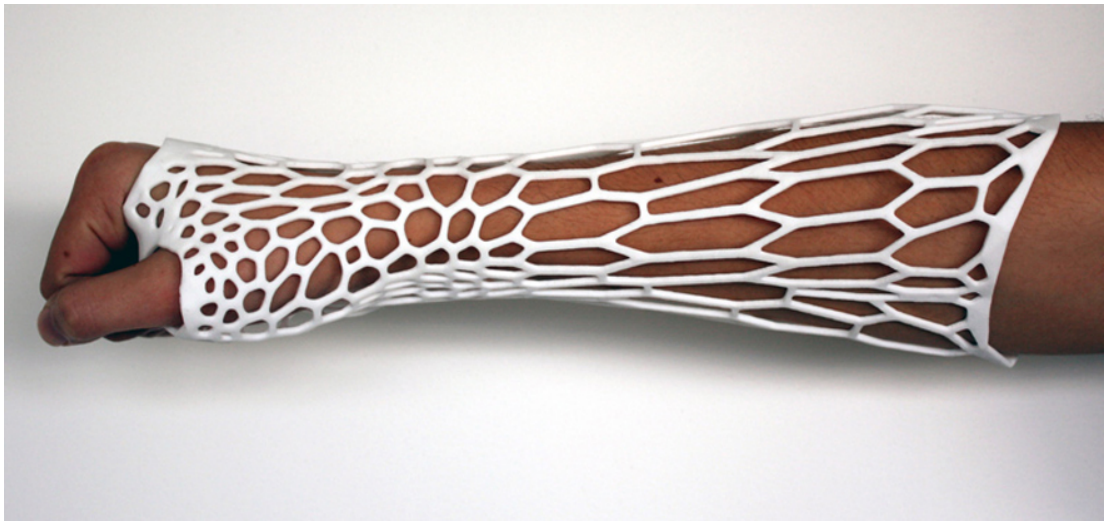
Outline

- 3D Printing Overview
- FDA Additive Manufacturing Working Group
- What have we cleared so far
- What are our concerns
- FDA research projects

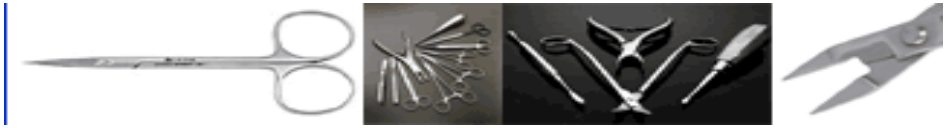
The First 150 Items You Encounter in an Emergency Room are probably Medical Devices





Risk-Based Classification of Medical Devices

- Class I: simple, low risk devices
  - General controls
  - Most exempt from premarket submission



Risk-Based Classification of Medical Devices

- Class II: more complex, higher risk
  - Special controls
  - Premarket Notification [510(k)]
  - Substantial equivalence
  - 10-15% require clinical data
  - 90 total FDA days to review

Cynic's View of Substantial Equivalence

Risk-Based Classification of Medical Devices

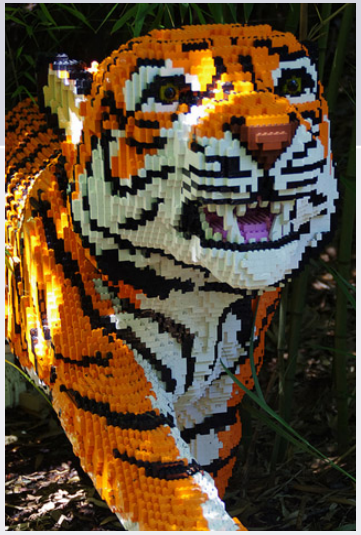
- Class III: most complex, highest risk
  - Premarket Application [PMA]
  - Establish safety and effectiveness
  - Bench - Animal - Human
  - May include post-approval study requirements
  - 320 total FDA days to review

Investigational Device Exemptions (IDE)

- Patient protection and clinical study design considerations

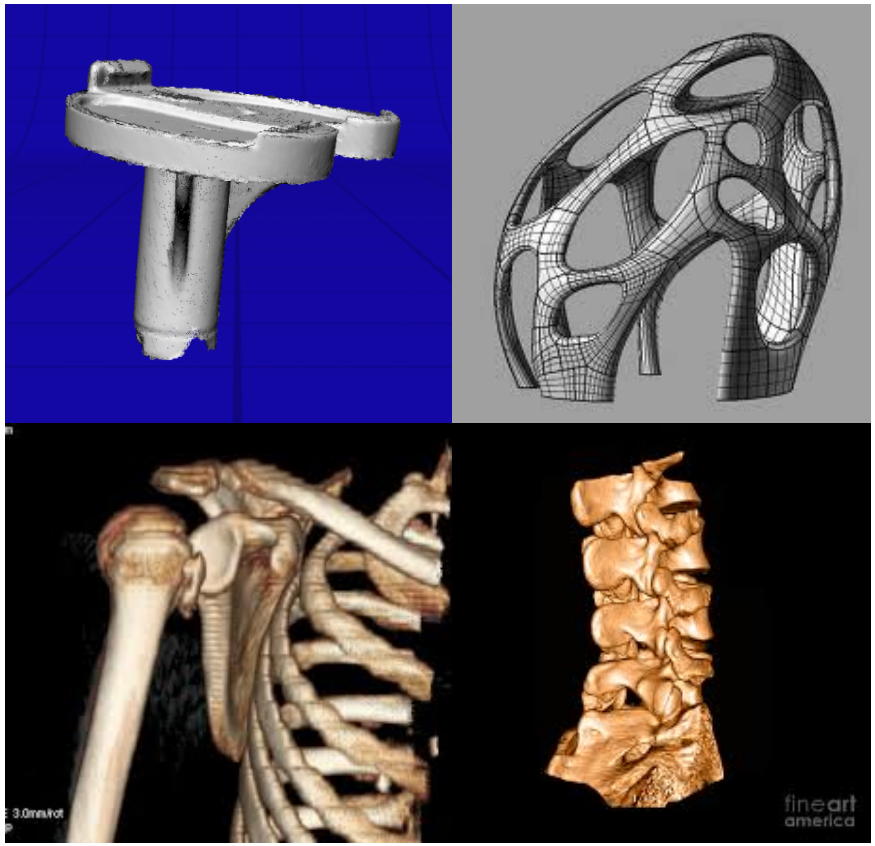
- Humanitarian Device Exemption (HUD)
  - (< 4K patient/year)
- Emergency Device Clearance

Subtractive (Traditional)	Additive (3D printing)
Removes material • Cutting • Drilling • Turning (Lathe) • Milling	**Adds material** • Builds layer-by-layer • Only puts material where necessary • Uses additional support material
Uses static molds • Cast • Forged • Injection • High throughput	**Rapid changes** • No molds • No tooling • Digital models • Small batches
Designed once • Established manufacturing and regulatory pathways	**Matched to patients** • Design processes and limits are evaluated



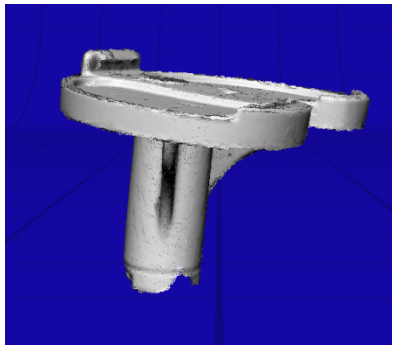
Digital Design → Conversion to Print Code → Printing

- Create part using engineering drawing software
- Patient anatomy can be accounted for via MRI/CT Scanning
- Porosity or internal reinforcements can be added

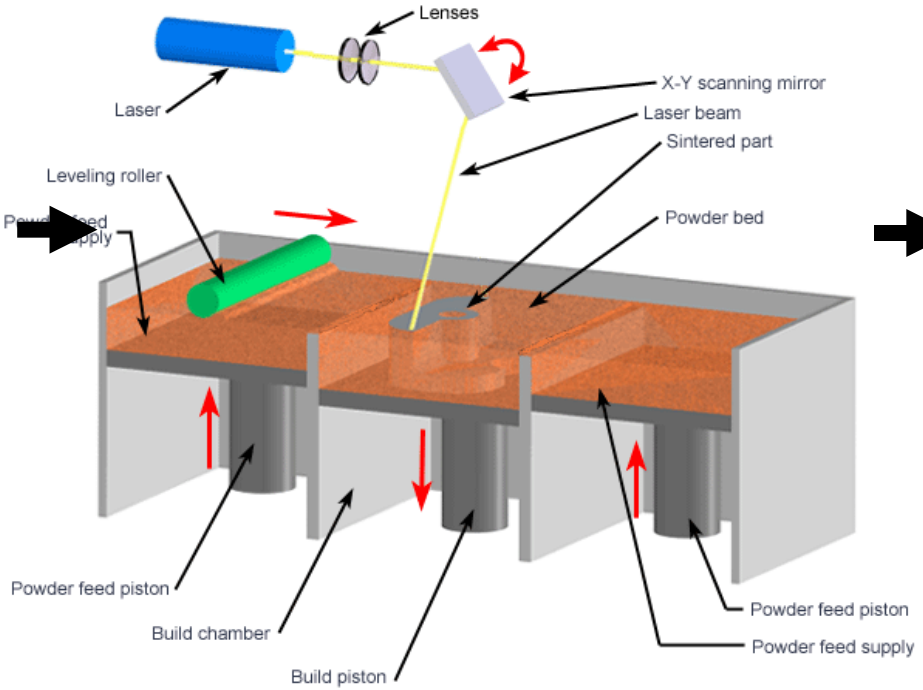


Digital Design → Conversion to Print Code → Printing

Entire component (comprising solid & porous features) built layer-by-layer from a digital model



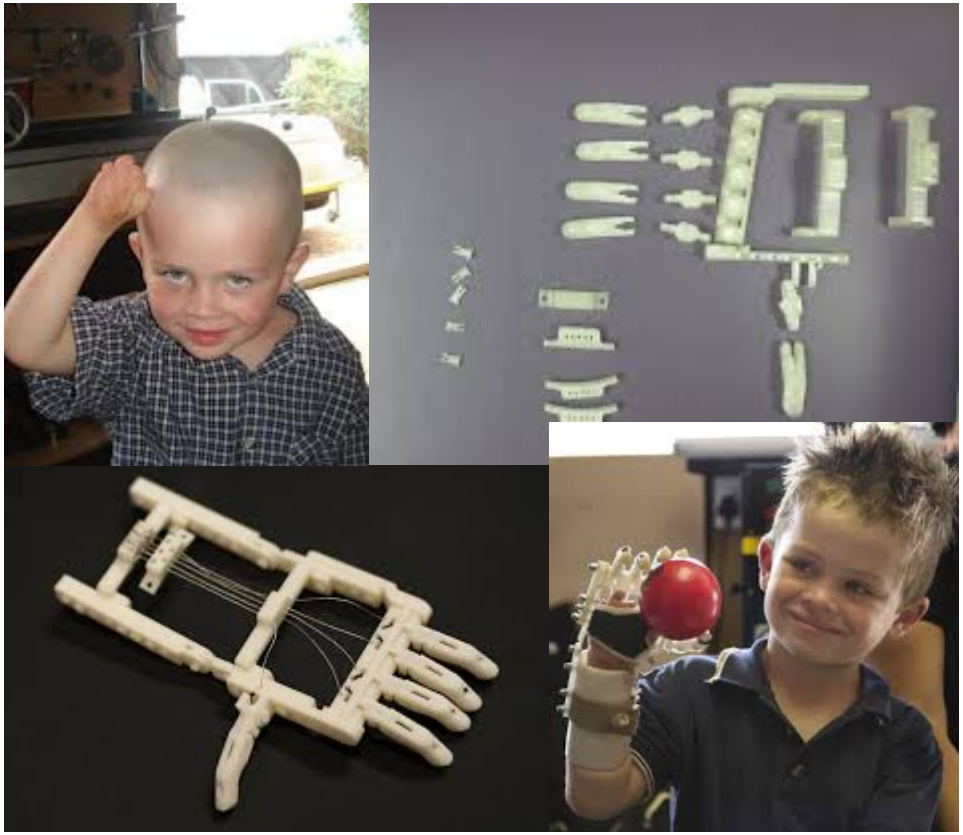
Digital model



Component

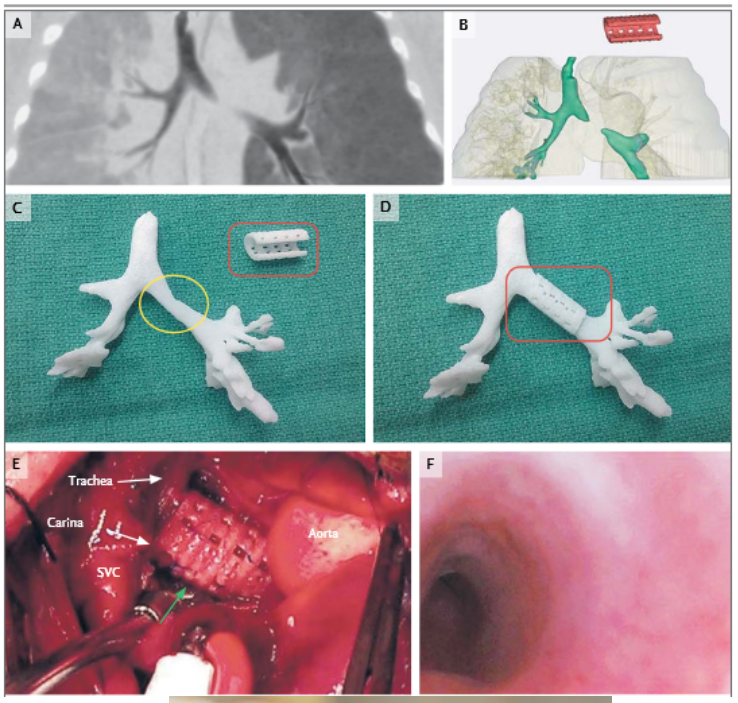
Robohand

- Designed in 2012 to address need for prostetics for children suffering from amniotic banding syndrome
- Using open source software and a low cost commercial printer, a mechanical prosthetic hand can be made to the proper size
- Allows for a quick, low cost alternative to traditional prosthetics near the patient
- Unpowered hand prosthetics are Class I devices, exempt from pre-market review (CFR 890.3420)



Trancheobronchomalacia

- Baby's bronchus collapsed regularly
- CT Scan taken of bronchus and splint designed from of patient anatomy
- A tracheal splint was 3D printed from degradable polymer, designed to degrade over 3 year
- Successfully removed off ventilator after 21 days
- Received emergency device clearance from the FDA

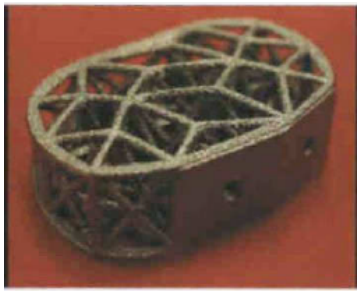


Zopf, David A. et al - Bioresorbable Airway Splint Created with a Three-Dimensional PrinterPT - Journal ArticleDP - 2013TA - New England Journal of MedicinePG - 2043-2045VI - 368IP - 21AID - 10.1056/NEJMc1206319

Regulatory History: What have we cleared?

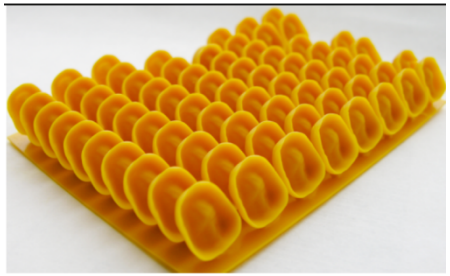
- Patient matched implants
  - Skull plate
  - Orthopedic implants
  - Emergency and custom devices

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



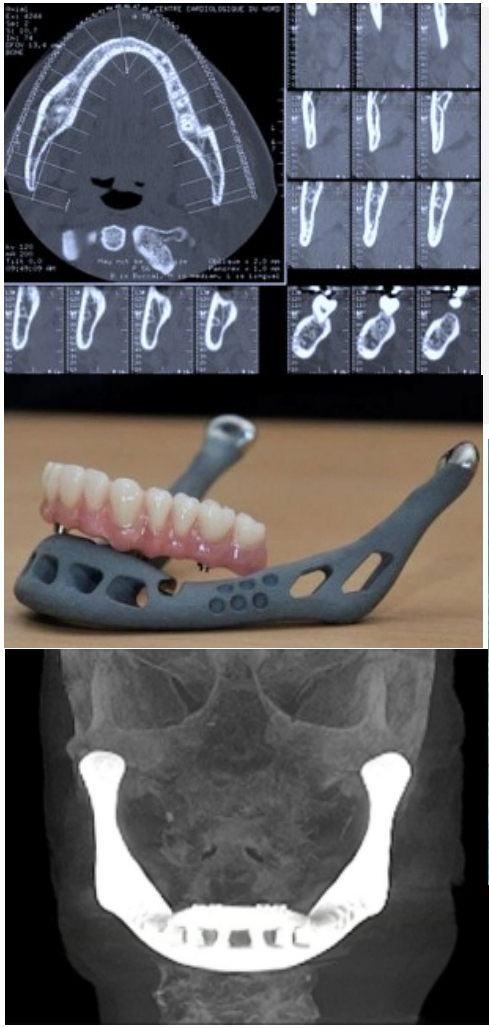
- Patient matched surgical guides
  - Craniofacial
  - Knee
  - Ankle

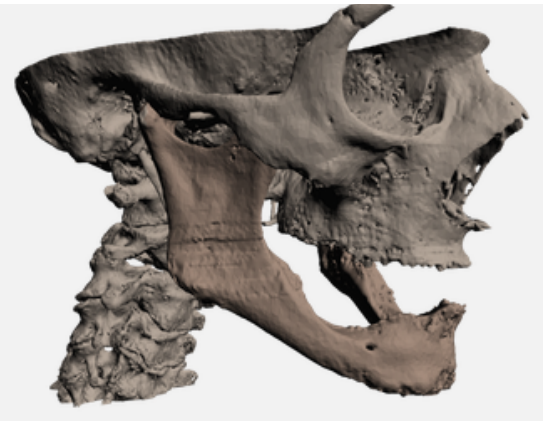
- Dental
  - Temporary bridges
  - Reconstructive surgery support

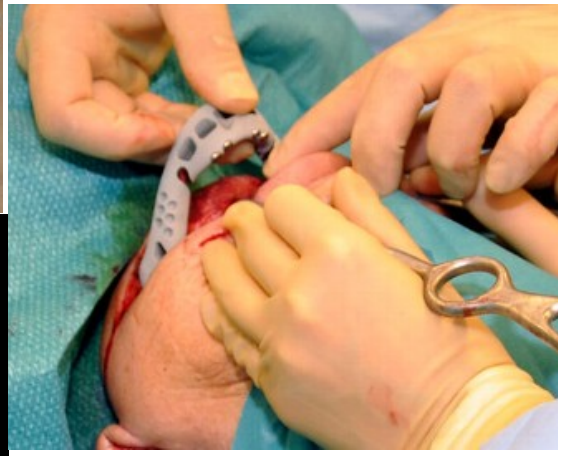


Total Jaw Implant

- In 2012 an 83 year old woman with osteomyelitis of the jaw had it replaced with a 3D printed titanium implant
- Patient had MRI so implant would be an anatomical match
- Jaw printed from titanium powder in a 2 day print
- Patient was eating, drinking, and speaking within 4 hours of surgery
- Outside of US, no FDA role



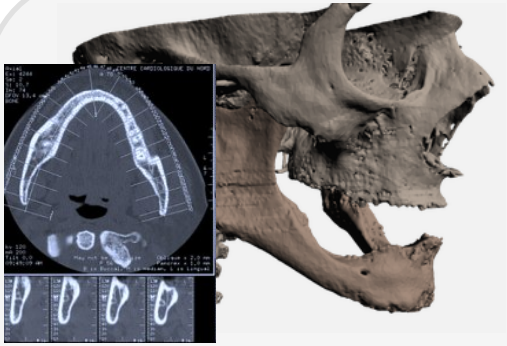




Liz Nickels, World's first patient-specific jaw implant, Metal Powder Report, Volume 67, Issue 2, March–April 2012, Pages 12-14,

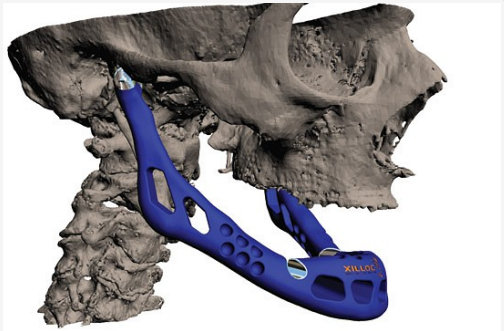
Considerations in a Submission

Imaging



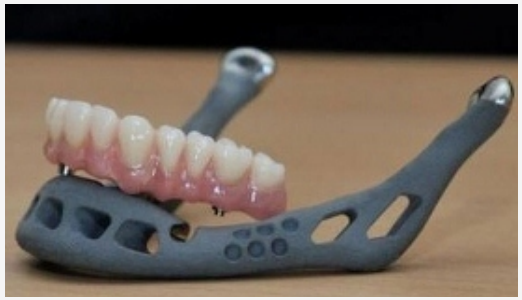
- Type of imaging
- Accuracy and resolution
- Post-processing

Digital Design



- The base model
- Algorithm to fit device to patient
- Design limits
- Key features

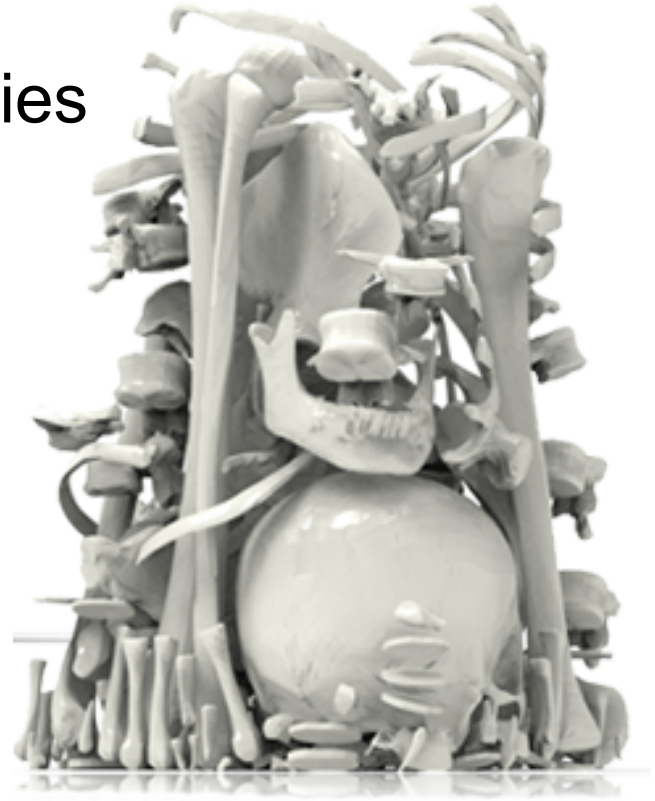
Printing

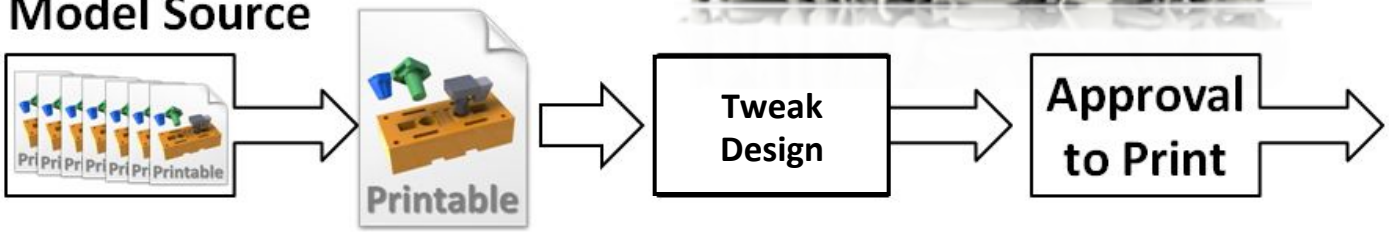


- Print parameters
- Biocompatibility
- Finishing steps
- Cleaning

Additive Manufacturing Considerations

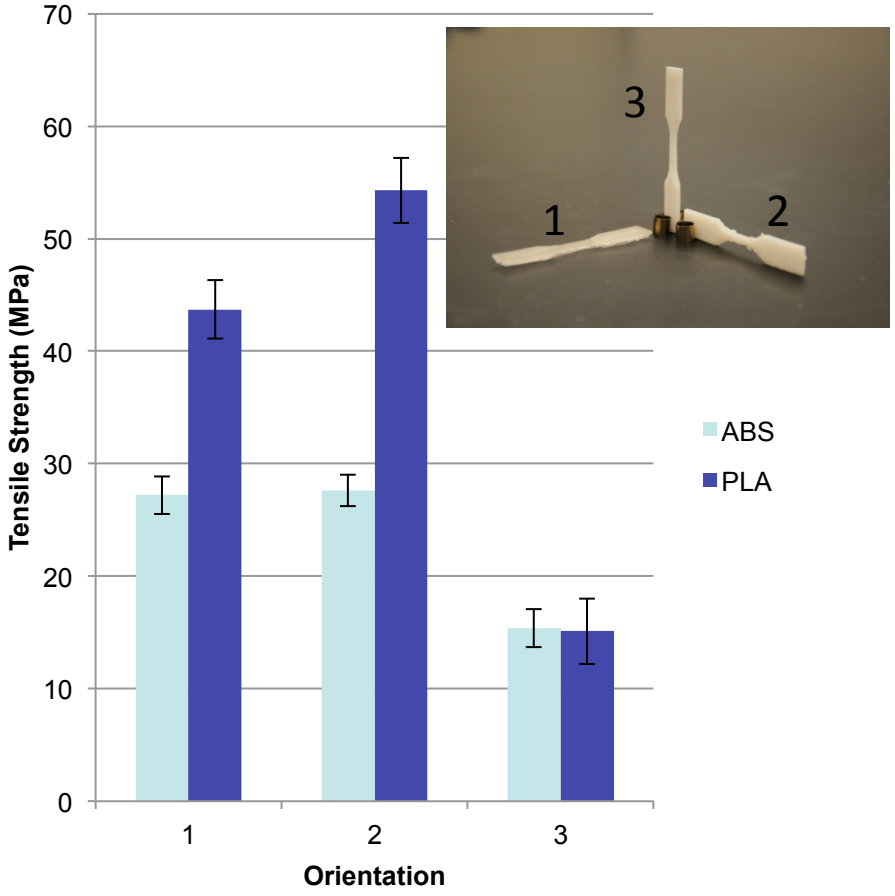
- Mechanical Properties
- Biocompatibility
- Design





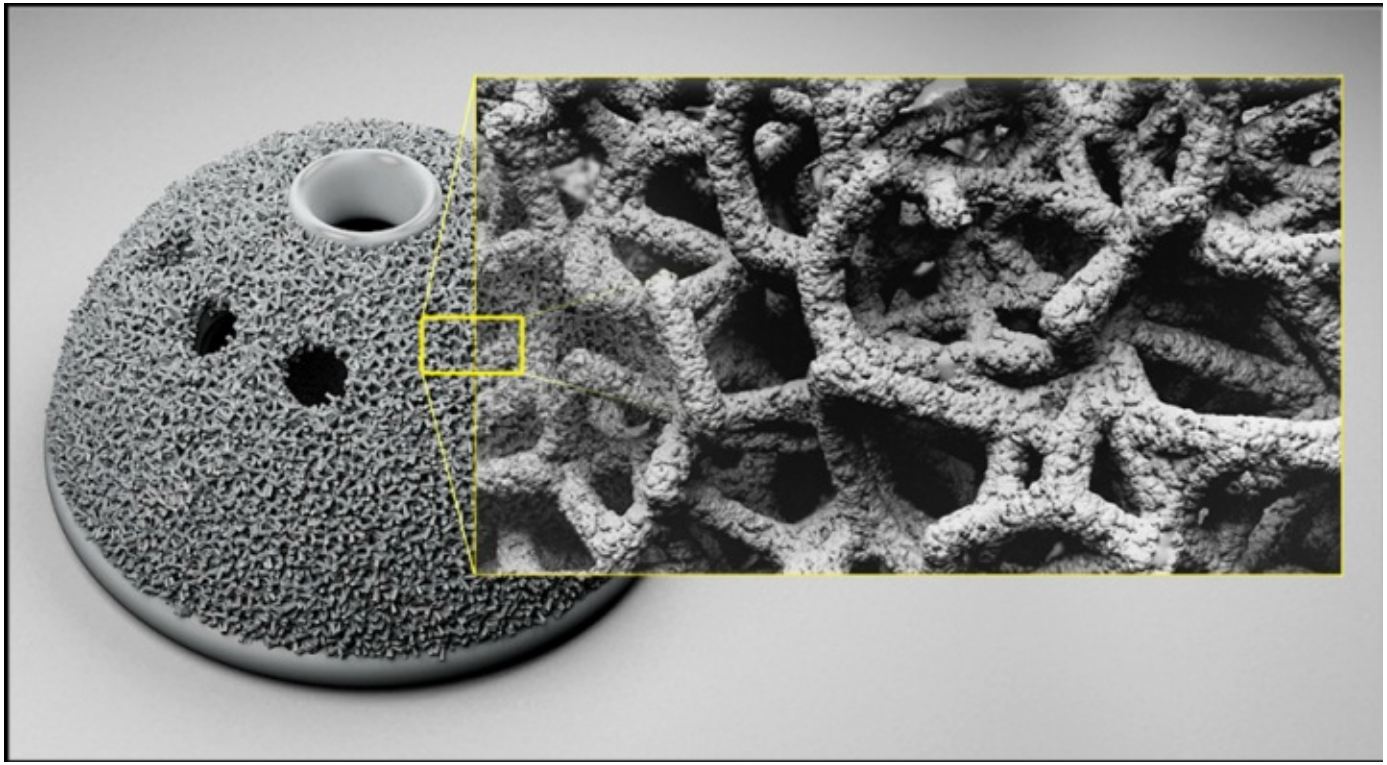
Considerations: Mechanical

- Printing process
  - Layering process creates directionality
  - Interface between layers can be a source of fatigue failure
- Post processing
  - Needed to relieve residual stresses from printing
  - Can positively/negatively affect performance



Considerations: Biocompatibility

- Cleaning of finished parts
- Material recycling



Considerations: Interactive Design

- Engineering v. Clinical Decisions
  - Drawing the line
  - Transparent and definitive outputs
  - Appropriate controls

- Design limitations
  - Continuously variable v. discrete sizes
  - Conveying the clinical effect of changes

Considerations: Production

- Design Validation
- Part Fidelity

Additive Manufacturing Working Group

Who We Are:

- Office of Science and Engineering Labs
- Office of Device Evaluation
- Office of Compliance
- CDER and CBER representatives

What We Do:

- Coordinate across CDRH
- Coordinate with CBER and CDER
- Improve consistency of review
- Policy
- Research prioritization
- Point of contact for Additive Manufacturing

FDA Research Projects

Critical Path Project

- Five modules addressing specific and immediate regulatory questions
- Organized by the cross-center AM working group
- Inform scientific decision making for regulatory submissions

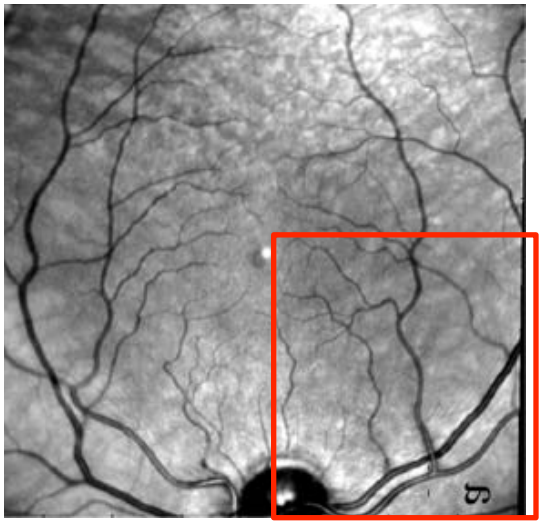
Commissioner's Fellowship

- 2 Year post-doc position
- Collaborative project between CDRH and CBER
- Focus on regulatory history and bio-printing

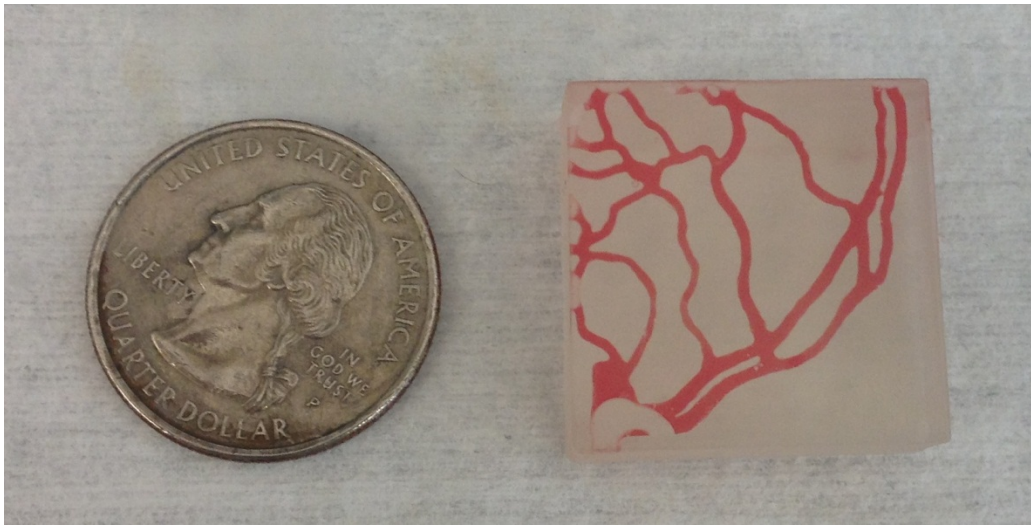
Critical Path Project

- How does print configuration affect mechanical properties?
- What are the regulatory requirements for 3D printable hydrogels?
- How can 3D printed models support and enhance diagnostic imaging validation?
- What biocompatibility tests are required and do the tests evaluate cleaning appropriately?
- Are patient-matched devices better and how can they be compared to standard devices?

3D-Printed Tissue-simulating Phantom for Optical Imaging System Assessment



Fundus photograph of human retina



Blood-vessel-simulating channels filled with Hb solution for hyperspectral imaging

J Pfefer and J Coburn (FDA), Y Chen and J Wang (UM-CP), J Ramella-Roman (FIU)

Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Considerations of 3-D Printing

October 8 and 9, 2014

The purpose of this workshop is to provide a forum for FDA, medical device manufactures, additive manufacturing companies, and academia to discuss technical challenges and solutions of 3-D printing. The agency would like input regarding technical assessments that should be considered for additively manufactured devices to provide a transparent evaluation process for future submissions.

Conclusion

- Most devices to date are reviewed through existing regulatory pathways
- The agency is proactively gathering expertise and developing policy to address this technology
- Additive Manufacturing holds great promise for personalized medicine and innovative medical solutions

Contact Us

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