



## **FDA/CDRH–RSNA SIG Joint Meeting on 3D Printed Patient-Specific Anatomic Models**

# **FDA Current Practices and Regulations**

**Nooshin Kiarashi, PhD**

**FDA/CDRH/Division of Radiological Health**

**August 31, 2017**

# 3D Printed Patient-specific Anatomic Models

## FDA Current Practices and Regulations



### Outline

- **Are 3D printed anatomic models medical devices?**
- **What is considered diagnostic use?**
- **How are they classified?**
- **What information is needed for clearance?**
- **Who has to obtain FDA clearance?**

# Scope

What 3D printed models are we talking about?

- 3D printed, patient-specific, anatomic models, generated via radiological imaging data (i.e. MRI, CT, Mammography, Ultrasound, X-ray)
- This talk does not address surgical templates, 3D printed parts intended to contact a patient, or QC phantoms

What software are we talking about?

- Software intended for diagnostic radiological use, specifically Picture and Archiving Communications Systems under the LLZ product code.
- Not covering Computer aided Detection (CADe), Computer Aided Diagnosis (CADx), or software intended to 'simulate/evaluate surgical treatment options or outcomes'.
- Software intended to simulate/evaluate surgical treatment option or outcomes is an accessory to the medical device it is simulating/evaluating and is outside the scope of LLZ and is reviewed by the group regulating the device that is being simulated/evaluated.

# Are 3D Printed Anatomic Models Medical Devices?



**Answer:** It depends on the intended use of the 3D printed anatomic model.

*FDA defines a **medical device** as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:*

*"... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ..."*

If 3D printed anatomic models are being marketed for **diagnostic use**, then they are considered a medical device.

# What Does DRH Consider to be Diagnostic Use for a 3D Printed Anatomic Model?



- Use that can affect/change
  - Diagnosis
  - Patient management
  - Patient treatment
- Examples:
  - Models used to make a diagnosis based on examination or a physical measurement of structural changes from the 3D model
  - Using the model to size and/or select a device or surgical instrument based on a comparison, fitting, or measurements with the model
  - Using the model to determine whether a specific surgical procedure may be viable

# What DRH Does Not Consider to be Diagnostic Use for a 3D Printed Anatomic Model?



- Use that does not affect/change
  - Diagnosis
  - Patient management
  - Patient treatment
- Examples:
  - Models used for communication/training to provide an example of anatomy or a specific condition, but aren't used as part of a specific patient's care
  - Patient-specific models used to explain and discuss a condition or procedure with an individual patient



# How are 3D Printed Anatomic Models Classified?

- Classified based on intended use, risk, and predicate device existence
- Diagnostic Intended Use – Class II
  - Intended for adjunctive use along with radiological images (MRI, CT, US, etc.) for diagnosis, patient management, and/or treatment selection.
  - Inaccurate models could mislead the physician resulting in a misdiagnosis, delayed treatment, or patient mismanagement.
  - Models may be found substantially equivalent to software generated 3D models/segmentation of anatomy for image analysis and measurement which can be achieved with performance testing
- Not a Medical Device
  - Not intended for diagnostic use
  - Not subject to general controls (registration and listing, GMP, etc.)
  - No risk to patient; use does not impact diagnosis or patient management



## Example Product Codes

### **Not Suitable** for 3D Printed Anatomic Models

21 CFR 892.1950

#### **Radiographic anthropomorphic phantom (IXG)**

- Identification: a device intended for medical purposes to simulate a human body for positioning radiographic equipment.
- Not a suitable product code because this 3D anatomic model is used for general quality assurance and is not patient-specific or intended for diagnostic use.



# Example Product Codes

## **Not Suitable** for 3D Printed Anatomic Models

21 CFR 888.4800

### **Template for clinical use (HWT)**

- Identification: a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.
- Not a suitable product code because it is for class I, 510(k) exempt devices which do not include the use of patient-specific anatomy or utilize special controls/validated performance testing to ensure the accuracy and precision of the model is adequate for diagnostic use.



# Example Product Codes

## **Suitable** for 3D Printed Anatomic Models

21 CFR 892.2050

### **Picture archiving and communications system (LLZ)**

- Identification: a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.
- This is a suitable product code for 3D printed anatomic models because validated performance testing exists to add this functionality to image analysis software devices to ensure that 3D printed anatomic models have adequate accuracy and precision to be of diagnostic quality when compared to their digital equivalents.



## Suitable Product Code: LLZ

- LLZ encompasses all software products for viewing, manipulating, and processing medical images.
- This includes segmentation, volume rendering, 3D display and measurement capabilities.
- A 3D printed patient-specific anatomic model that is intended for diagnostic use is, in essence, a physical representation of a digital model that is produced by such software.



# What Information is Needed for 510(k) Clearance?

- Validation for the intended use to ensure adequate diagnostic quality.
- Extent of validation will be dependent on specific diagnostic use.
- Validation will have to address accuracy and reproducibility.
- Recommended 3D printer, material, and post-processing should be provided.
- Scope of clearance will be based on the provided validation.



# What Information is Needed for 510(k) Clearance?

Performance testing can include but is not limited to:

- Clinically relevant accuracy and precision measurements for a specific anatomy type (i.e. dental, knee, spine, cardio-vascular, etc.)
- Phantom based testing to ensure detectable landmarks are accurately replicated in 3D printed anatomy
- 3D printer compatibility if claiming compatibility with more than one printer model/manufacturer



# Who Has to Obtain FDA Clearance? The 3D Printer Manufacturer?

- **Yes**, if the 3D printer manufacturer plans to market the software associated with the printer as being capable of outputting 3D printed anatomy intended for diagnostic use.
- **No**, If the 3D Printer manufacturer is marketing their device for general 3D printing and not specifically for medical uses.



# Who Has to Obtain FDA Clearance? The Software Developer?

- **Yes**, If the software is intended and marketed to output files for 3D printing anatomic models for diagnostic use.
- **No**, If the software clearly states that 3D printed models created from its digital outputs are not for diagnostic use or is not capable of outputting 3D printable file formats (i.e. STL files).

# Who Has to Obtain FDA Clearance? The Clinic/Facility Utilizing 3D Printer and Software?

**Yes:** The clinic/facility is marketing software that **is not** cleared for 3D printing anatomic models for diagnostic use.

- The clinic/facility is marketing a software regulated by the FDA, making them a device manufacturer and as such should submit a 510(k).

**No:** The clinic/facility is marketing the ability to output patient-specific 3D printed anatomy for diagnostic use and the used software **is** cleared for that intended use.

- The clinic/facility is using the software as intended and cleared by the FDA, there is no issue.

**No:** A doctor requests a 3D printed patient-specific anatomy for diagnostic use to aid with a special case he is currently working on from their hospital, but the software used **is not** cleared for that intended use.

- The hospital **is not** actively marketing 3D printing services for diagnostic use. The doctor requested the model to aid in treatment of the patient under the practice of medicine. FDA does not regulate the practice of medicine.



# **FDA/CDRH – RSNA SIG Joint Meeting on 3D Printed Patient-Specific Anatomic Models**

## **FDA Current Practices and Regulations**

**Thank you**

**Questions/Comments**