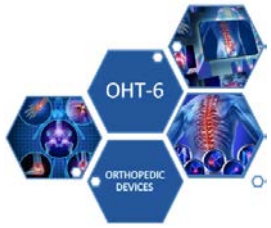

FDA U.S. FOOD & DRUG ADMINISTRATION

Changes to an Existing Device

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DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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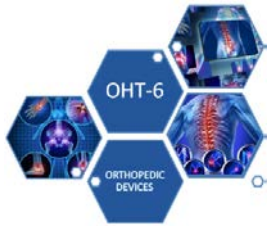
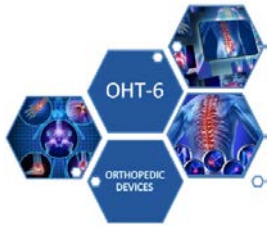


Outline

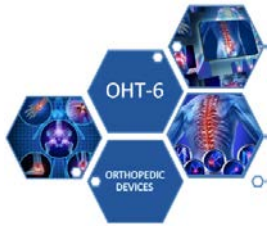
Requirements to Consider:

- FDA Guidance Document: Deciding When to Submit a 510(k) for a Change to an Existing Device found at: https://www.fda.gov/media/99812/download
- Examples of when new 510(k) is and is not required
- Reporting changes in the 510(k)



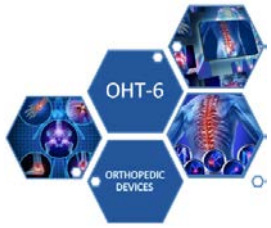
FDA's Guidance

- Deciding When to Submit a 510(k) for a Change to an Existing Device
- FDA CDRH LEARN
- Guidance include guiding principles for evaluating changes
- Main types of changes:
  - Labeling
  - Technology, Engineering, or performance
  - Materials
- Evaluate risk profile



Determination

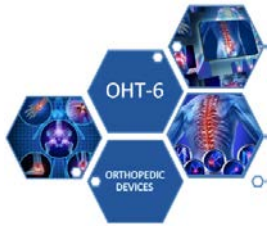
- Consider impact of device modification(s) on device labeling, technology/engineering/performance, and/or materials
- Provide an assessment of each change as well as the cumulative assessment of all changes to the device compared to the previously cleared device
- If testing has been done, that does not necessarily mean a new 510(k) is needed



Examples

- Device Modifications that generally do not require a 510(k) Submission:
  - Introducing intermediate sizes of the **same** design
  - Tightening the tolerances on engineering drawings
  - Administrative labeling changes

- Device Modifications that generally would require a 510(k)
  - Change in materials
  - Switching from a subtractive to additive manufacturing process
  - Changing sterilization method

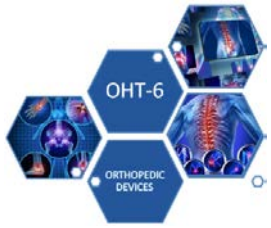


Reporting Modifications

- When a new 510(k) is submitted for a device with multiple changes, that 510(k) should describe all changes that trigger the requirement for submission of a new 510(k).

- 510(k) should also describe other changes since the most recently cleared 510(k) (i.e., those that did not require submission of a new 510(k)) that would have been documented as part of the first 510(k) for that device.

- Even if a device modification does not introduce a new worst-case, or performance testing demonstrates equivalent performance, a 510(k) is still required if the new design goes beyond the dimensions/design of the unmodified predicate device.



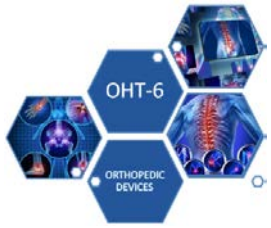
Bundling

Requirements to Consider:

- FDA's guidance document: Bundling Multiple Devices or Multiple Indications in a Single Submission (found at: https://www.fda.gov/media/73500/download)

- Can bundle changes to multiple devices if:
  - The supporting data are similar
  - Primarily one review division/group will be involved
  - Devices or Indications for Use are similar

- Agency can unbundle submissions if we disagree based on the guidance document



Bundling Examples

- It would be acceptable to bundle a submission in which you are changing sterilization method (e.g. going from moist heat steam sterilization to gamma) for multiple product areas such as cages and pedicle screw systems.

- It would not be acceptable to bundle a submission in which you are seeking clearance for two different product areas such as lumbar cage and a pedicle screw system.

Thank You!

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