510(k) Device Modifications Case Study

FDA Small Business Regulatory Education for Industry (REdI)

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Melissa Hall

Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration


Cervical Spine

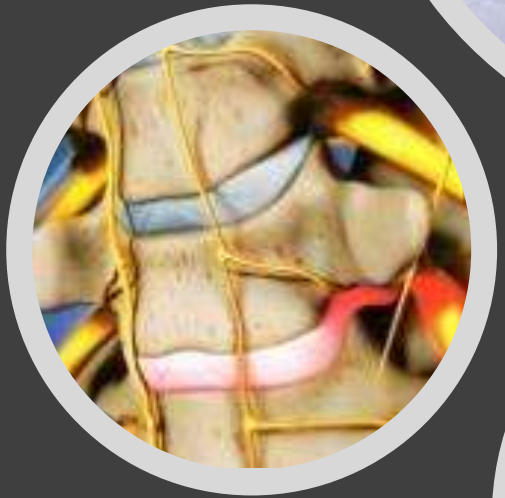
Learning Objectives

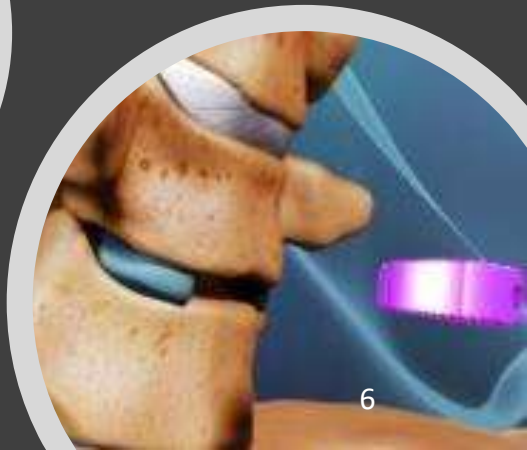
1. Introduce the Case Study-Modification to an intervertebral body fusion device.
2. Describe the risk-based assessment process.
3. Highlight key steps to deciding when to submit a 510(k) for a Change to an existing device.

Case Study:
Intervertebral Body Fusion Device

What are Intervertebral Body Fusion Devices (IBFs/Cages)

A device that is inserted into the intervertebral body space of the cervical thoracic, or lumbosacral spine, and is intended for intervertebral body fusion.

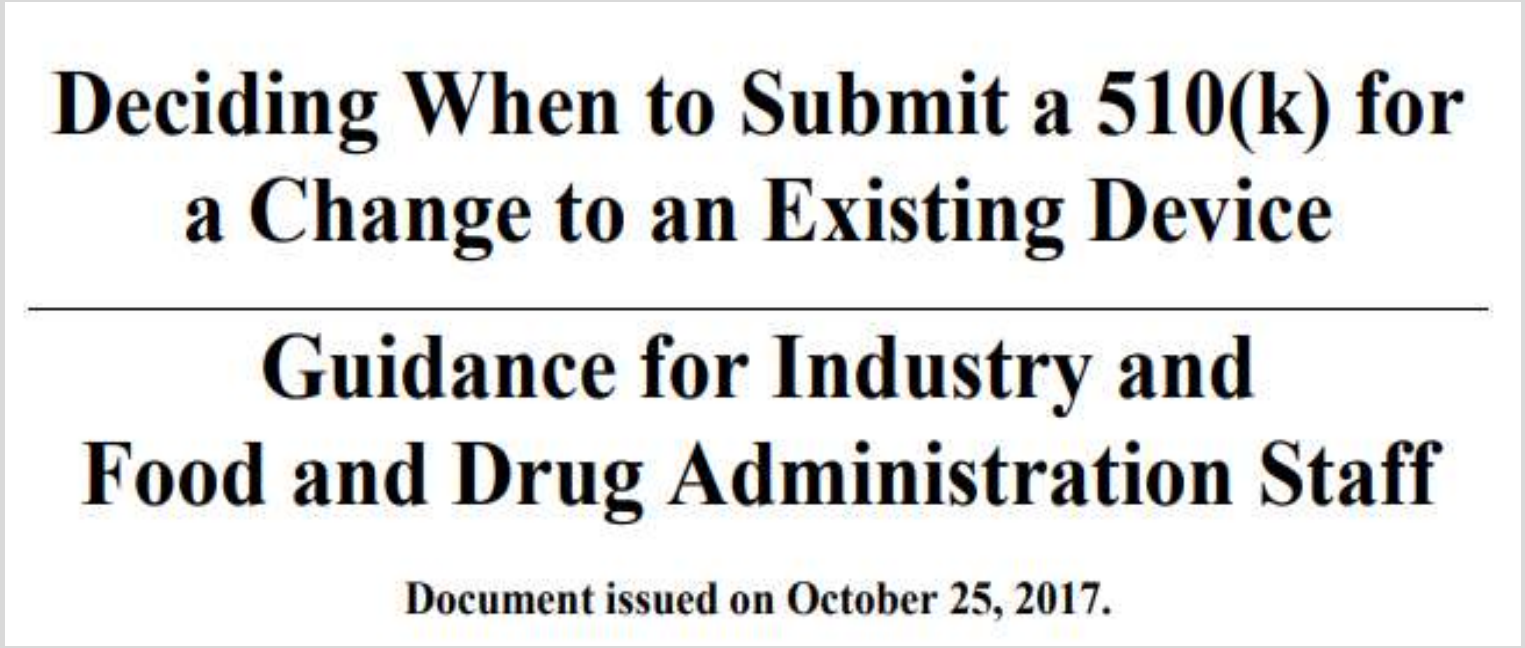




Case Study Scenario

Manufacturer wants to add a bigger size to accommodate the anatomical differences in vertebral body sizes.

Do I Need a New 510(k)?



Deciding When to Submit a 510(k) for a Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 25, 2017.

Deciding When to Submit a 510(k) for a Change to an Existing Device
21 CFR 807.81(a)(3)
21 CFR 820

When is a 510(k) Required for a Change?

- Significant changes or modifications in design, material, chemical composition, energy source, or manufacturing process that:
  - **Could significantly affect the safety or effectiveness.**
  - **Change or modify** the intended use of the device.

21 CFR 807.81(a)(3)

Types of 510(k) Modifications

- Labeling
- Technology, Engineering, and Performance
- Material
- Technology, Engineering, and Performance of In Vitro Diagnostics (IVDs)

Knowledge Check

What category of device modification would a change from non-sterile packaging to sterile packaging belong?

a. Material

b. Technology, Engineering, and Performance

c. Labeling

d. None of the above

Understanding the Risk-Based Assessment Process for Medical Device Modifications

- Intend modification to significantly affect safety or effectiveness
- Unintended consequences
- Potential hazards, failure modes, or circumstances
- Sequences of events
- Probability of hazardous situation

Example of Risk-Based Assessment

Device Modification	Risk	Hazardous Situation(s)	Consequences	Risk Control Measure(s)	Risk Acceptability Criteria	Verification & Validation Method	Summary Conclusion
Adding a larger device size	Potential to create new worst-case	Device breakage	Additional surgeries Pain and loss of function	Finite Element Analysis (FEA) Mechanical testing	Compare mechanical testing results to unmodified FDA cleared device	Testing conducted in the same manner (criteria, parameters, sample size)	New worst-case or not?

Knowledge Check

A manufacturer makes multiple changes to a device:

- **One** change triggers the requirement for submission of a new 510(k),
- **Three** changes do not require submission of a new 510(k)

Can the three changes be immediately implemented?

a. Yes

b. No

c. I don't know

Flowchart B: Technology, Engineering, and Performance Changes

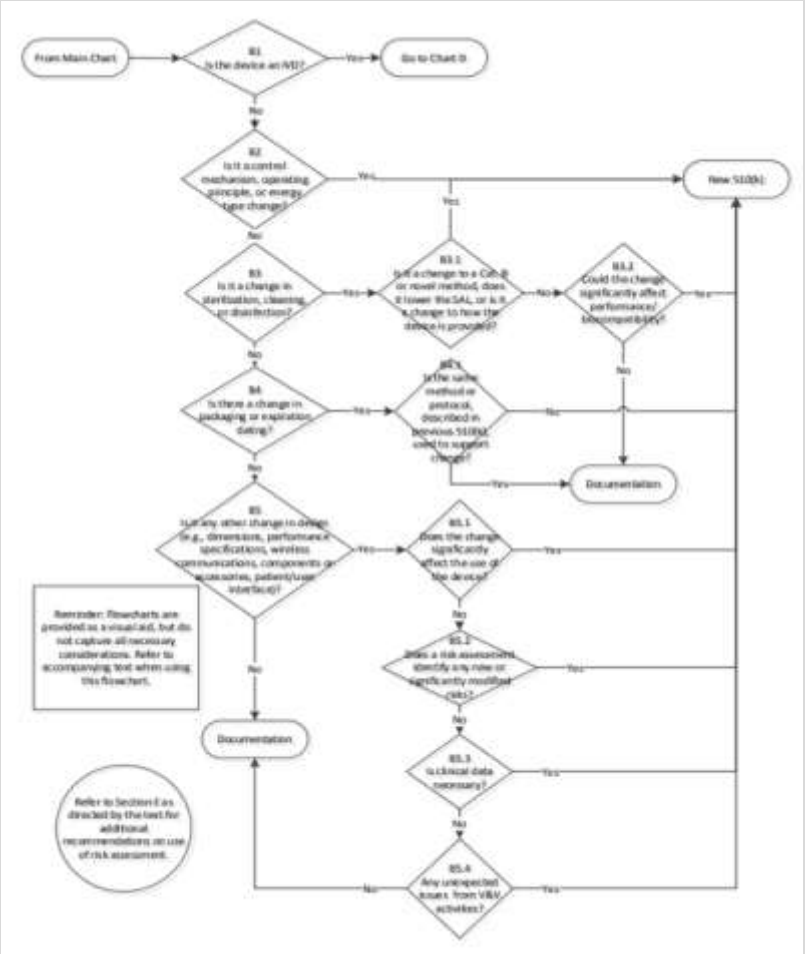
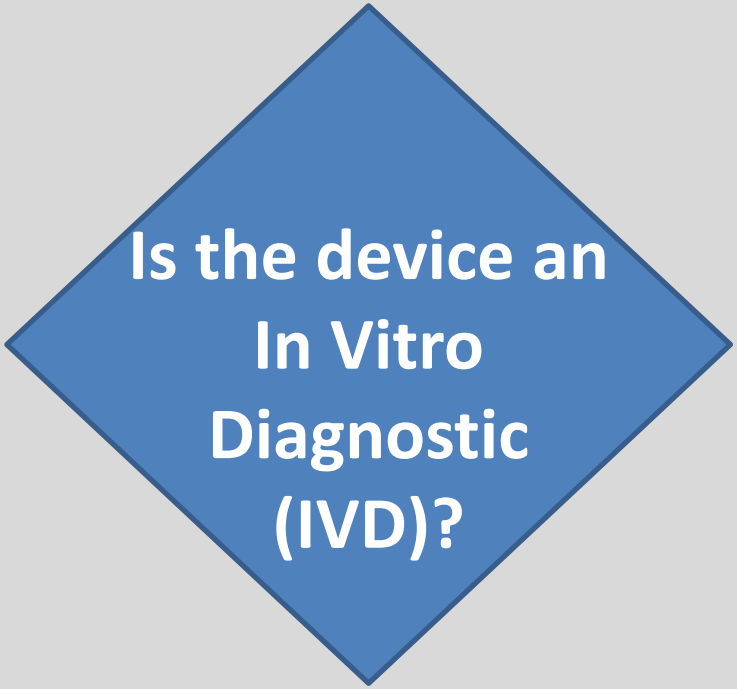
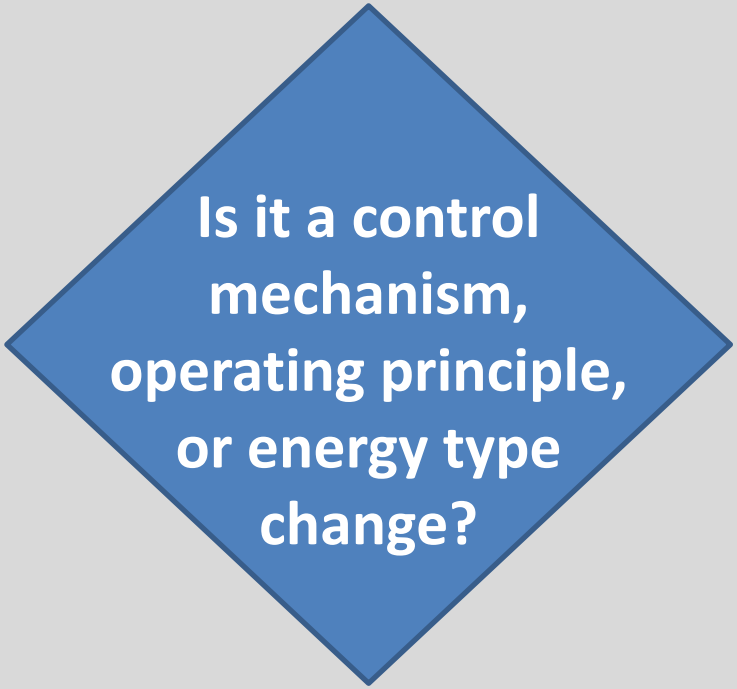


Figure 3 - Flowchart B: Technology, Engineering, and Performance Changes

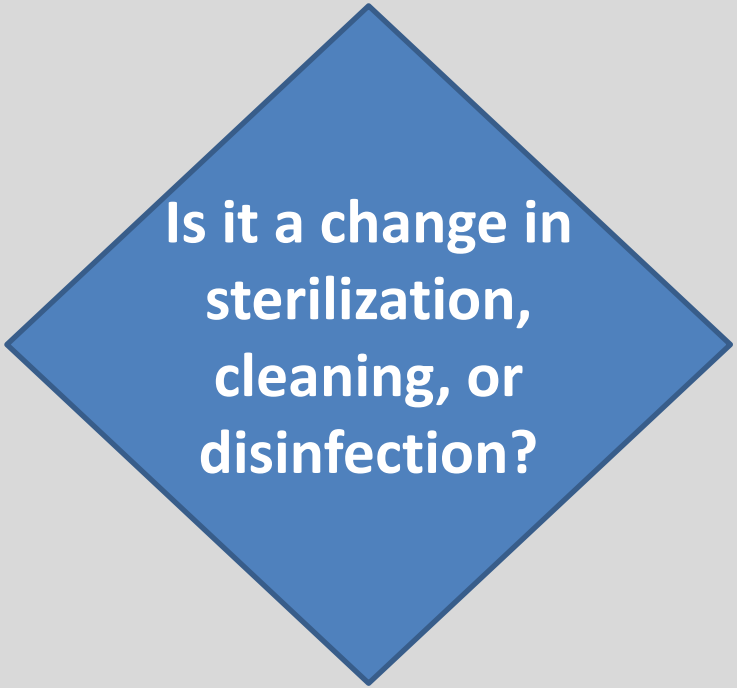
Flowchart B: Decision Point 1



Flowchart B: Decision Point 2

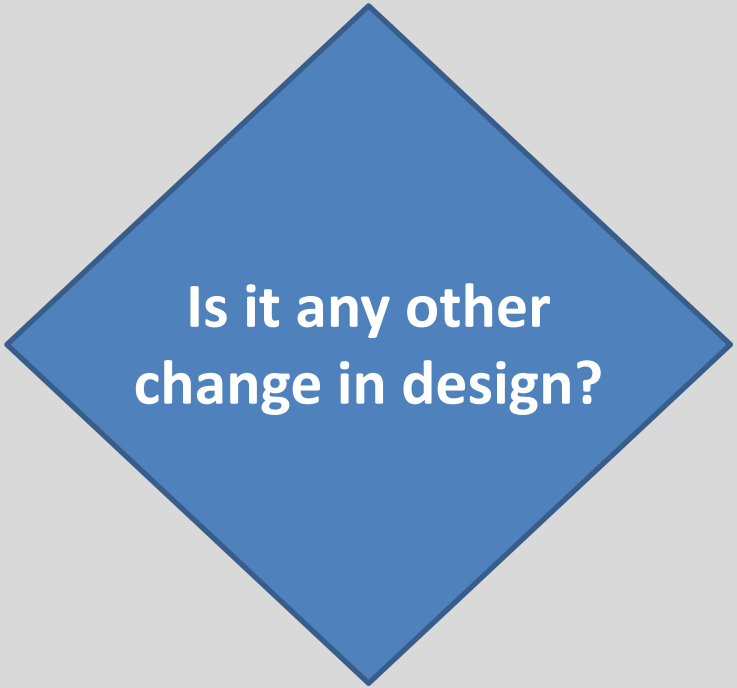


Flowchart B: Decision Point 3

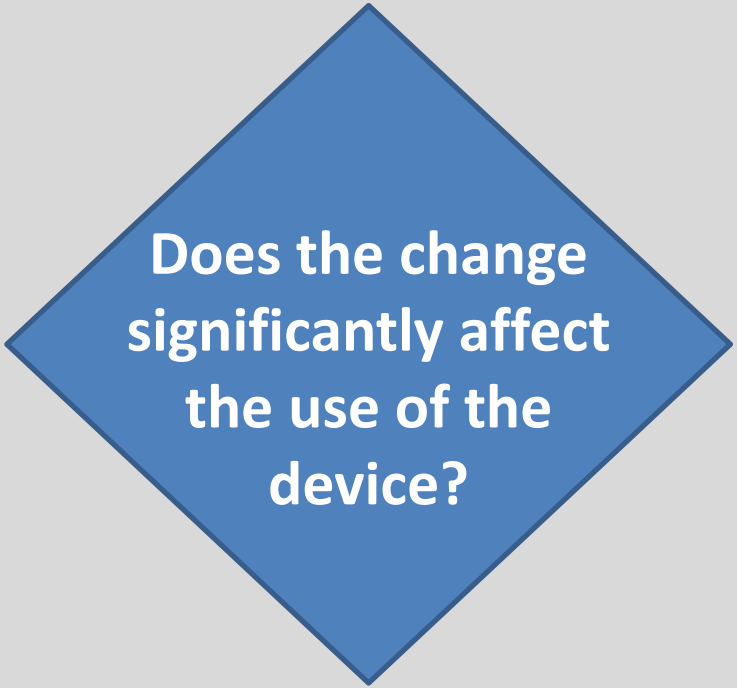


Flowchart B: Decision Point 4

Flowchart B: Decision Point 5



Flowchart B: Decision Point 5.1

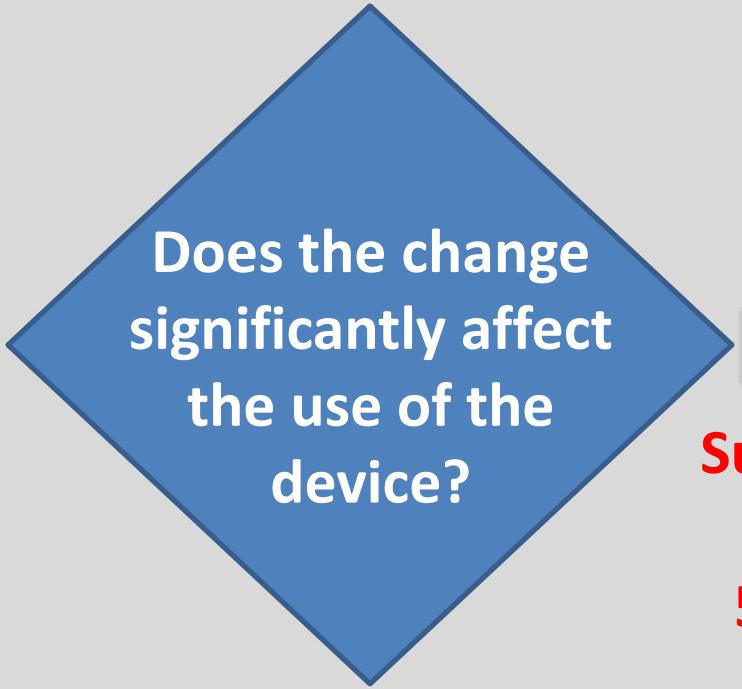


Flowchart B: Decision Point 5.1

Does the change significantly affect the use of the device?

	Cleared Device Sizes	New Device Size
Cervical Cage size	12x14, 14x16	15x17

Flowchart B: Decision Point 5.1



YES

Submit a New 510(k)

- **Added size is outside the parameters of the previously cleared 510(k)**
- **Change in dimension could significantly affect the safe or effective operation of the device.**

Substantial Equivalence

Device Modification	Risk	Hazardous Situation(s)	Consequences	Risk Control Measure(s)	Risk Acceptability Criteria	Verification & Validation Method	Summary Conclusion
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- Will the new size create a new worst-case in terms of mechanical strength?
- Will the failure mode be different?
  - Conduct Mechanical Testing

Determining Submission Type

Traditional 510(k), Special 510(k), or the Safety and Performance Based Pathway?

Things to consider:

- Can you provide the performance data in summary format?
- Are there well established methods and/or acceptance criteria?
- Minor deviations to the testing protocols?

How to Document Modifications

When submitting your 510(k) you should document the device modifications as well as other changes since the last 510(k) clearance in the:

- Cover letter
- Executive Summary
- Substantial equivalence determination

Summary

1. Introduced a real device modification example case study.
2. Described how to utilize the tools available to conduct a thorough risk-based assessment of the modification
3. Highlighted how to use the conclusions of the risk-based assessment to:
    - Identify the type of change
    - Use the appropriate flowchart, and
    - Determine whether a new 510(k) is needed for your modification

Resources

Resource Type	Resource Title	URL
FDA Guidance	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
FDA Guidance	Format for Traditional and Abbreviated 510(k)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks
FDA Guidance	The Special 510(k) Program	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program
CDRH Learn Module	CDRH Learn Module: 510(k) Program	http://fda.yorkcast.com/webcast/Play/d91af554691c4260b5eca0b2a28e636b1d
Device Advice Webpage	Premarket Notification 510(k)	https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
Device Advice Webpage	510(k) Format Tips	https://www.fda.gov/medical-devices/premarket-notification-510k/510k-format-tips
Device Advice Webpage	Content of a 510(k)	https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k

Questions


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