510(k) Modifications

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Industry's Perspective

Draft Modifications Guidance

Draft Guidance

- Deciding When to Submit a 510(k) for a Change to an Existing Device, issued Aug. 8, 2016
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device, issued Aug. 8, 2016

Current State: K97

- Published in 1997 and not updated since
  - Relied on GMPs
  - QSR…just coming into effect
  - Design controls…a concept
- Areas for improvement
  - Documentation expectations
  - Flow charts: a tool, not an outcome
  - Cumulative effect of changes; burdensome expectations
  - Materials changes chart somewhat confusing

Moving Forward: 2016 Draft

- Builds on K-97
- Role of Quality System in change management recognized and defined
- Incorporation of risk management principles
- Flow charts: use with accompanying text
- Software modifications addressed in separate guidance
- Valuable examples

Moving Forward: Considerations for Revised Guidance

- Labeling Section:
  - Assessing modifications
    - "Major change or modification in intended use" or substantive change in indications for use
    - Could change affect the indications for use

Documenting Decisions to File or Not File

Documentation

Good Documentation Practices

- Govern with a standard operating procedure
- Properly document all regulatory decisions related to a 510(k) change
- Provide sufficient context and detail for independent reader to understand the decision

Good documentation practices

- General
  - Date of assessment
  - Product name
  - Product indication
  - 510(k) number
- Describe change
  - Change category
  - Scope of the change
  - Relative to the cleared 510(k)
  - Reason for the change

Good Documentation Practices

- Change assessment (Decision-making Process)
  - How decision attained
  - Mirror the considerations discussed in the guidance for the change type
  - Respond to questions in guidance
  - Provide a rationale or discussion when it is not readily apparent that the answer is yes or no
- Basis for conclusion
- Reference related documents
- Signature and date of an individual qualified to make the assessment

Change Complexity

- Different levels of documentation appropriate depending on change complexity
- Establish as part of governing SOP
- Simple documentation appropriate for simple changes:
  - Modification of company labels to update to new company name
  - Raw material supplier changes that only modify the reference number or brand name of the raw material

Documentation Examples

Check Box

☒ **PART A – LABELING CHANGE**

A1. Does the change affect indications for use?	☐ Yes, 510(k) R	☒ No, go to A.2
A2. Is it a change in warnings or precautions?	☐ Yes, 510(k)NR	☒ No, go to A.3
A3. Does the change add a contraindication?	☐ Yes, 510(k)R	☒ No, go to A.4
A4. Does the change delete a contraindication?	☐ Yes, 510(k)R	☒ No, go to A.5
A5. Is the labeling being revised for clarity or insure safer or more effective use?	☒ Yes, 510(k)NR	☐ No, 510(k)R

If A5 is Yes, summarize the basis for the decision in comments section below.

Narrative

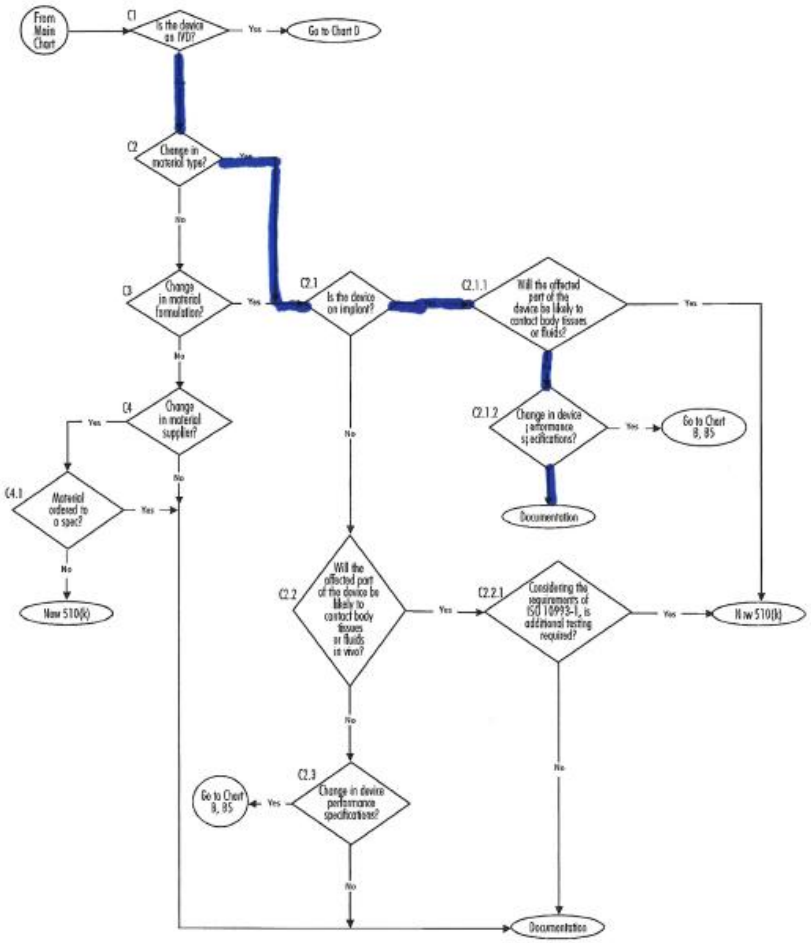
Design and dimension changes were made to the outer case to better match the housing design of other products in this product family. These are cosmetic changes that do not raise any significant safety or effectiveness questions. No other design and dimension changes have been made. These changes do not affect the indications for use or require clinical data to assess the changes.

Comparison Table

Element	From	To
Material	Stainless Steel	No changes
Coating	Coating applied to proximal and distal tips	Coating removed, increasing the surface amount of Stainless Steel
Intended Use	"This product is intended for use with…"	No change

Knowledge Check

FLOWCHART C - IS IT A MATERIALS CHANGE?



Knowledge Check

Regulatory Change Assessment

Product Name: Device C1000
Date of Assessment: 9/1/16
Description of Change: Labeling
Reason: Clarify instructions for use
Recommended Regulatory Action:
Letter to File

Thank You