Manufacturer Perspective:

FDA Draft Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device

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FDA Draft Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device

Draft revision to the January 10, 1997 Guidance of the same name. Issued for Comment July 28, 2011.

1997 Version

- Due to Recall or Corrective Action?
- Labeling Change?
- Technology, Engineering or Performance Change?
- Materials Change?

2011 Version

- Manufacturing Process Change?
- Labeling Change?
- Technology, Engineering or Performance Change?
- Materials Change?
- Is Clinical Data Necessary?

New or Modified Threshold(s)

New:
Manufacturing Process Changes

- New starting point: Questions related to Manufacturing Process Changes.
- New question to consider: Was manufacturing process information part of the original 510(k) submission?
- Other questions extracted from Technology, Engineering and Performance Changes.

Concerns

- Does device specific guidance supersede this general guidance?
- Will there be a transition period for documenting new questions?

New or Modified Threshold(s)

Modified: Materials Changes

- Significantly reduced from 1997 version [16 questions (including IVD specific questions) compared to 3 questions].
- Key question: Does the change affect patient-contacting materials (either direct or indirect)?
- New question : Does the change involve the device surface?

Concerns

- New 510(k) submission will be required for changes to all non-implant patient contacting materials. This includes changes from well characterized material to another well characterized material (example: AISI 400 stainless steel to AISI 316 stainless steel).
- How will past decisions under the 1997 guidance to document the change (no new 510(k)) be treated?

New or Modified Threshold(s)

New Section: Is clinical data necessary to determine substantial equivalence?

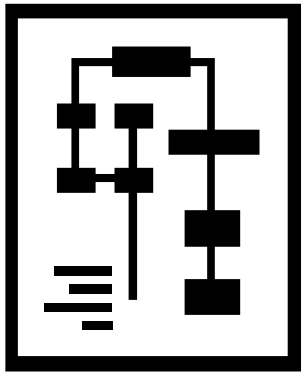
- Moved from Technology, Engineering and Performance Changes section of 1997 guidance (question B8.2).
- Expands scope: “not only data acquired from prospective, controlled clinical trials, but includes any data derived from human subjects. “

Concerns

- A medical device manufacturer often performs clinical studies which are not intended to determine the safety or efficacy of a device, but are done for other reasons:
  - Consumer preference studies
  - Testing of a combination of devices in a medical procedure

Key Questions for Industry

What is the appropriate level of documentation?



Can I reconstruct the basis of reasoning/logic of this decision?

a month from now?

a year from now?

at my next inspection?