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FDA DRAFT GUIDANCE ON SOFTWARE AND OTHER DEVICE CHANGES

Medtronic
Further, Together

BACKGROUND ON DRAFT GUIDANCE DOCUMENTS

- Existing guidance dates from 1997
  - Very little information on evaluating software changes
  - Written prior to implementation of the QSR
  - Risk management for medical devices only in its infancy
- FDA issued a previous draft guidance around 2011
  - Very prescriptive, not well received by industry
  - Did not leverage QSR
  - Withdrawn by FDA
- FDA decided that there should be two separate documents
  - One dedicated to SW changes
  - One for all other changes
  - Produced by two different teams

STAKEHOLDER INPUT INTO CURRENT DRAFTS

- Through FDASIA, Congress required FDA to gather stakeholder input into new draft of the K97-1 replacement
  - AdvaMed "Mods Squad"
  - 510(k) Coalition
  - "Medtronic & Friends" team (started summer 2014)
  - Potentially others
- Software-specific guidance has always been a joint effort between a sub-group at AdvaMed and a sub-group at ODE
- Multiple face-to-face meetings with stakeholders
  - AdvaMed and Medtronic-led team both submitted detailed proposals for K97-1 replacement
  - There have been additional meetings since the drafts were issued
- Comment process is still underway

OVERVIEW OF CURRENT DRAFT- GENERAL
COMPARISON TO K97-1

- Similarities
  - Same general topics in scope (labeling, technology/design/materials/IVDs)
  - Many of the key decision making questions remain the same
- Differences
  - Major role for risk management
  - Much clearer on need to notify of significant improvements, not just potentially increased risks
  - Much more detail on how to document no-file decisions

COMPARISON OF THE TWO DRAFT DOCUMENTS
GENERAL VS SOFTWARE

- Share the same Guiding Principles
- Both use a risk-based approach
- Key differences in the details of risk management
  - General guidance starts with considering likelihood that change could have an effect – if likelihood is negligible, no further analysis needed
  - Software guidance considers primarily the severity of the associated harm
  - Software change only leads to 510(k) if there is a potentially severe harm - no such limits in the general guidance
  - Software guidance considers adequacy of existing risk controls when reaching the 510(k) decision – general guidance does not

POTENTIAL BENEFITS OF GUIDANCE DOCUMENTS

- General Guidance
  - Guiding Principles give a framework for evaluating all types of changes
  - Risk-based approach allows each manufacturer to consider impacts on their specific devices
  - Certain "gotcha" questions have been removed (e.g., was biocompatibility testing needed?)
  - Confirms that the same logic scheme applies to pre-amendment devices
- Software Guidance
  - Changes limited to cybersecurity patches and bug fixes can be implemented without 510(k) , if no other impacts
  - Also uses risk-based approach
  - Detailed background section on how to evaluate when code changes are significant

CHALLENGES OF GUIDANCE DOCUMENTS

- First question on "significant improvement" is not well defined – no examples
- No clear relationship between general guidance and SW guidance – many times will have to apply both
- Different risk management questions and criteria may be difficult to manage
  - Generally have to consider SW risk as part of a system
  - Could reach two different conclusions for a set of interrelated changes that include software, hardware, and/or labeling
  - No obvious justification for the more generous approach in SW guidance
- Documentation expectations related to change evaluation
  - Some new challenges cannot be eliminated
    - Postmarket risk management activities
    - Need to expressly compare to 510(k)-cleared or pre-market design
  - Some can and should be addressed through comments
    - "Simple" documentation example very burdensome for most changes
    - Cumulative evaluation needs to be clarified or removed

POINTS OF CONCERN RAISED TO FDA – DOCUMENTATION

- Documentation guidelines could be read as requiring letter-to-file for even very minor changes
  - Very minor changes are those that do not affect labeling, design, technology, specifications, or materials (defined as "documentation" on Main flowchart)
  - Usually process-related or documentation only (e.g., note on a drawing)
  - The great majority of changes are in this category
- Proposed that the guidance clarify that these sorts of changes do not require formal regulatory documentation as part of change control
- FDA appeared to understand the concern and willing to add clarifications
- Medtronic is submitting formal comments on this topic
- Strongly suggest that others amplify this message

DOCUMENTATION CONCERNS, CONT'D.

- The list of elements to include in the documented regulatory evaluation is extensive and includes extraneous information
  - Device description as opposed to just change description
  - Full regulatory history rather than just most recent 510(k)
  - References to supporting documents that are irrelevant for many change evaluations
  - Examples appear to include discussion of previously implemented changes, even if irrelevant for evaluation of the current change
- Guidance appears to expect that all of the listed information will be in the regulatory evaluation
  - Would require repetition of information from change request/change order
- Medtronic is submitting comments to request
  - Limiting the information to relevant details
  - Allowing the regulatory documentation to include or refer to the location of required information
- Strongly suggest others amplifying this message

POINTS OF CONCERN RAISED TO FDA – CUMULATIVE EVALUATION

- The Guiding Principles section refers to the need to consider cumulative changes but does not provide guidance on how this should be done
- The documentation examples imply the need to list previously implemented changes
- This can become a very burdensome activity, even if cumulative evaluation is limited to only a subset of changes
- Medtronic's position is that
  - Most previous changes are irrelevant when considering an additional change
  - There is no value in maintaining a list or revisiting previous no-file decisions
  - If the regulatory evaluation consistently goes back to the last cleared 510(k), any relevant previous changes will automatically be considered during the risk assessment and other design control activities
- Medtronic is submitting comments to this effect. Similar comments from other companies will help to amplify the message.

POINTS OF CONCERN RAISED TO FDA – GENERAL VS SOFTWARE

- Because the two guidance documents will both apply in many cases, relationship needs to be defined
  - Medtronic has suggested that SW be considered subsidiary to the main guidance
- Differences in risk management approach should be resolved
  - At meeting, Medtronic recommended that the SW guidance point back to the general guidance for risk management – do not think that this will be adopted
  - Written comments will include
    - Suggestion to align on a single harm level across both documents
    - Suggestion to consider the adequacy of existing risk controls for all types of changes
    - Clarify that new 510(k) is not needed if existing risk controls (in 510(k)-cleared design) reduce new or modified risks to acceptable levels
- Suggest you discuss with your software and risk management teams – consider if you want to submit comments

OTHER POTENTIAL CONCERNS

- First question in main flow chart
  - Change made with the intent to significantly improve the safety or effectiveness of the device (e.g., in response to a known risk, adverse event, etc.)?
  - Is it clear enough without additional guidance or examples?
  - Medtronic is not submitting comments on this point; AdvaMed will suggest removal of question
- References to "routine V &V"
  - Concern is that any variation in the test plan or protocols could be seen as not using "routine" testing and potentially triggering 510(k)
  - FDA admitted to struggling with the wording
  - Medtronic is submitting a comment to remove the word routine; AdvaMed suggesting "appropriate."
- Unexpected test results – impact on 510(k) decision
  - Medtronic is commenting that such a situation requires re-evaluation, not necessarily a new 510(k)

HOW TO COMMENT

- Don't just point out problems – provide an alternative. Explain why the alternative meets the goals of the guidance document.
- A cover letter is helpful. Try to point out positive aspects in the cover letter. Clearly identify who is commenting and name the draft guidance document
- Follow this with detailed comments
- Suggested format:

Line(s) No.	Change	Reason
List numbers from the line-numbered draft document	State what the change should be. Examples: Delete a specific word or sentence Add clarifying text Replace existing text with new proposed text	Why is the draft confusing, overly burdensome, or incorrect? How does your proposal better? Help FDA see why the changed text is consistent with the goals of the guidance document – identifying when a change has significantly affected the device and adequately documenting no-file decisions.

WHERE AND WHEN TO COMMENT

- Go to Regulations.gov
- Use the established FDA Dockets
  - FDA-2016-D-2021-0001 for the general modifications document
  - FDA-2011-D-0453-0043for the software modifications document
- If you can also find the dockets via key word search on regulations.gov
- Comments must be submitted by November 7, 11:59 PM ET
- Note that your comments are public records – do not list any proprietary information