

document be revised to include computed tomography scanners and magnetic resonance imaging devices.

FDA agrees to expand the candidates list as requested and has amended table 1 of the FDA guidance document accordingly.

(Comment 3) Two comments requested that members of the GHTF coordinate the execution of the pilot program in their respective jurisdictions by including the same device categories and conducting the pilot program simultaneously. The comments suggested posting information about the pilot program on the GHTF Web site. Concern was expressed that the draft STED document will lead to an increase in the type and amount of information submitted in premarket applications.

FDA agrees that the pilot premarket program should be coordinated with other members of GHTF to the extent possible, and has made efforts to do so. FDA will work with the GHTF secretariat and the Chair of SG1 to post appropriate information regarding the pilot program on the GHTF Web site. FDA is sensitive to the concern that a harmonized format may recommend different or additional information from that customarily submitted in premarket submissions. The draft STED format is one means of normalizing the information submitted to many different regulatory authorities. The short-term effect may indicate some imbalances in the regulatory burden from one country to another, but the long-term expectation is that the benefits will outweigh any short-term effects and will be significant. FDA believes that harmonization of administrative and technical requirements is desirable; the GHTF's role in the STED pilot program is supplemented by the strength of its efforts in standards development activities, bilateral partnerships, and mutual recognition activities.

(Comment 4) Another comment requests clarification of the information needed to be included in the premarket submission for each Essential Principle and asks if every Essential Principle must be addressed. The comment also requests clarifications on terminology with respect to labeling.

The premarket submission should identify the Essential Principles that are applicable to the device and provide conformity information as explained in sections 7.1.1 and 7.1.2 of the draft STED document. It will not necessarily be the case that all Essential Principles will be applicable to a particular device. In addition, there may be more than one way to conform to an Essential Principle, e.g., by meeting a standard or

demonstrating laboratory results from an appropriate bench test.

FDA agrees that the draft STED document should have clarifications with respect to labeling terminology and instructions for use. FDA will ask SG1 to consider this comment when it assesses the results of the pilot program.

(Comment 5) Two comments ask FDA to clarify which of the Essential Principles would be relevant in a premarket submission prepared using the draft STED format. They ask whether FDA intends for premarket submissions, based on the draft STED format, to be submitted in a tabular format as shown in Appendix B of the draft STED document and, if so, whether the table needs to be supplemented with supporting information.

FDA expects premarket submissions prepared using the draft STED format to identify and reference all applicable Essential Principles, as explained in sections 7.1.1 and 7.1.2 of the draft STED document. Also, 510(k) submissions and premarket approval applications (PMAs) relying on the draft STED format must still address all applicable FDA requirements for 510(k)s or PMAs. With regard to format, the basic format for preparing a harmonized premarket submission is described in sections 6.1 and 6.3 of the draft STED document (see also section VII of the final FDA guidance). Each part of the submission can be subgrouped as described in section 7.0 of the draft STED document. Section 7.1.2 suggests that one method to format evidence of conformity information may be in tabular form as shown in the sample table in Appendix B of the draft STED document. Supporting information should be provided as needed regardless of format, particularly if recommended in a product-specific guidance. FDA accepts declarations or statements of conformity to FDA-recognized standards. Use of such declarations or statements may provide a benefit to a manufacturer by decreasing the amount of supporting documentation that needs to be submitted.

(Comment 6) Another comment notes a possible incorrect cross-reference in table 3 of the draft FDA guidance with regard to standards.

FDA has eliminated table 3 and has clarified the section.

(Comment 7) Three comments state that a risk analysis is not included in 510(k) and PMA submissions and therefore should not be included in harmonized premarket submissions using the draft STED document.

FDA has announced new guidance that includes a risk analysis in some

510(k) submissions. (See <http://www.fda.gov/cdrh/modact/special-controls.html>). A goal of the premarket harmonization process is to achieve a common submission in terms of format and content for all five participating members of the GHTF. Although FDA may not require a risk analysis for a new 510(k), it is a common request in other countries. Therefore, it is prudent for a device manufacturer intending to market a device globally, and who intends to use the draft STED format, to include a risk analysis in the submission.

(Comment 8) One comment asks for clarification of the note under table 2 of the draft FDA guidance concerning manufacturing information.

FDA has eliminated table 2 and clarified the information elsewhere in the document. The FDA final guidance document notes that manufacturing information will not be needed for 510(k)s using the draft STED format during the pilot program, unless that information would otherwise be submitted under current procedures for a particular device.

(Comment 9) One comment requests the draft STED document include links between the class of a device and the parameters applicable to the Essential Principles of safety and performance. The comment suggests changing the title of section 7.3 from "Summary of Design Verification and Validation Documents" to "Summary of Design and Verification Data." The comment notes the title could imply the need for more documentation than what is intended.

FDA will ask SG1 to consider this comment when it assesses the results of the pilot program.

(Comment 10) One comment recommends the use of promissory statements when a regulatory authority requires country-specific information beyond that described in the draft STED document.

FDA accepts statements of conformity to recognized standards. These statements indicate a device meets a particular standard. FDA has no other provisions for promissory statements.

(Comment 11) Another comment notes that the draft STED document and appendices refer to data and information not usually submitted in 510(k)s and PMAs. It suggests there be an indication of the information not applicable for these types of submissions to minimize the submission burden.

FDA agrees with the comment and has noted that manufacturing information is not ordinarily required in a 510(k) application. Hence this information would not be needed in a