Summary Technical Document (STED) Pilot Program

The Center for Devices and Radiological Health (CDRH) is encouraging submitters of premarket approval (PMA) applications and premarket notifications (510(k)s) to participate in the ongoing voluntary STED Pilot Program.

What is “STED”?  
The Summary Technical Document (STED) format for regulatory submissions is a harmonized submission format developed by the Global Harmonization Task Force (GHTF), a voluntary partnership of government and industry representatives from the United States of America and four other member states: Australia, Canada, the European Union, and Japan. GHTF promotes international harmonization of medical device regulation through the preparation and distribution of guidelines such as the proposed STED format. The proposed harmonized format and content is described in the document titled, “Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices,” which represents the proposed STED document. The document was developed by Study Group 1 (SG1) of GHTF and issued as a proposed document on December 16, 2003. While the use of the STED format is still in its early stages, it has the long-term potential to standardize the format of regulatory submissions across jurisdictions. The STED harmonized submission format is already accepted by multiple regulatory authorities worldwide.

What is the STED Pilot Program?  
In June 2003, CDRH implemented a voluntary pilot premarket review program intended to assess the feasibility of the STED format and content for certain PMA applications and 510(k) submissions. During the pilot, the GHTF “draft STED document,” together with the FDA Guidance titled, “A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures,” will serve as an alternative to the submission procedures described in previous FDA guidance documents. This program will continue until CDRH receives a sufficient number of STED-formatted applications to allow a conclusive evaluation of the suitability of this format.

CDRH encourages medical device manufacturers to participate in the STED Pilot Program. Manufacturers will benefit from exposure to the STED preparation process, especially those seeking international regulatory approval/clearance for their devices. In addition, greater industry participation in this program will increase CDRH’s familiarity with STED submissions and will allow CDRH to provide constructive feedback to GHTF on the current STED format.

What devices are eligible for participation in the STED Pilot Program?  
All of the review divisions within CDRH’s Office of Device Evaluation are currently participating in the STED Pilot Program. These divisions are:

- Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID)
- Division of Cardiovascular Devices (DCD)
- Division of General, Restorative, and Neurological Devices (DGRND)
- Division of Ophthalmic and Ear, Nose, and Throat Devices (DOED)

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/SummaryTechnicalDocumentSTEDPilo...
Examples of devices reviewed by these divisions that are eligible for STED submissions include:

- Intravascular catheters
- Implantable pacemakers
- Orthopedic implants
- Keratomes
- Magnetic resonance imaging devices

The STED format may not be appropriate for all devices, such as devices incorporating novel technology or new intended uses. You should speak with the appropriate review division prior to preparing your submission to determine if a STED submission is appropriate for your device.

What submissions are NOT eligible for participation in the STED Pilot Program?

Submissions that are not eligible for participation in the STED Pilot Program are:

- Special 510(k)s
- Submissions involving in vitro diagnostic (IVD) devices
- Product Development Protocols (PDPs)
- Humanitarian Device Exemptions (HDEs)

In addition, not all types of PMA supplements are eligible for participation. You should speak with the appropriate review division prior to preparing your submission to determine whether the STED format is suitable for your intended PMA supplement.

STED and Third Party Review

CDRH now allows Accredited Persons to review STED-formatted 510(k)s for those Class I and II devices that are also eligible for third party review. A list of devices eligible for 510(k) third party review is located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4.

For further information regarding the Third Party Review Program, please contact Mr. Eric J. Rechen at (301) 796-6562 or eric.rechen@fda.hhs.gov.

Contact Information

For further information regarding the STED Pilot Program at CDRH, please contact Mark Melkerson, at mark.melkerson@fda.hhs.gov or (301) 796-6383, or Kenneth J. Cavanaugh Jr., Ph.D., at kenneth.cavanaugh@fda.hhs.gov or (301) 796-6377.

Resources

- Guidance for Industry and FDA Staff: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071520.htm)

- Third Party Review
Global Harmonization Task Force (http://www.ghtf.org)
(http://AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)