24 Hour Summary
General and Plastic Surgery Devices
Advisory Committee Meeting
May 30, 2019

Introduction:

On May 30, 2019, the General and Plastic Surgery Devices Panel of the Medical Device Advisory Committee met to discuss and make recommendations regarding the reclassification of surgical stapler devices for internal use from Class I (general controls) to Class II (special controls). Surgical stapler devices are considered pre-amendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective.

Device Description:

The technology and use characteristics of surgical staplers for internal use have changed as the devices have become more complex and have evolved to match changing surgical methods. A surgical stapler for internal use is a specialized device used to deliver staples to internal tissues during surgery for removing part of an organ (i.e., resection), cutting through organs and tissues (i.e., transection), and creating connections between structures (i.e., anastomoses). It may be used in open, minimally invasive, laparoscopic and endoscopic surgery. Surgical staplers for internal use may be indicated for use in a wide range of surgical applications, including, but not limited to, gastrointestinal, gynecologic, and thoracic surgery.

Many types of surgical staplers for internal use exist, including, but not limited to,

- Transverse Approximators (TA): Staplers which apply rows of staples but do not cut, or linear non-cutting staplers.
- Gastrointestinal Anastomoses (GIA) linear cutting and stapling devices
- Endoscopic Gastrointestinal Anastomosis (endoGIA) staplers: articulating and non-articulating endoscopic cutting/staplers
- Circular or End to End Anastomosis (EEA) staplers, intended for circular cutting and stapling to create end-to-end, end-to-side, and side to side anastomoses.

Surgical staplers for internal use include both manual and powered staplers.

Summary of Presentations

The committee heard presentations from FDA about safety issues related to surgical staplers for internal use, and clinical considerations for these staplers. A summary of medical device reports

for surgical staplers and staples for internal use was presented. Additionally, FDA described the current review practice for surgical staplers for internal use and discussed the risks, mitigations, and special controls that FDA proposed. The committee heard a presentation from the ECRI Institute on surgical staplers, their analysis of the safety issues associated with surgical staplers and their support of reclassification of surgical staplers for internal use to Class II. Industry speakers representing Medtronic described the benefit of surgical staplers and expressed a willingness to work with FDA following the meeting to support FDA's efforts to regulate surgical staplers for internal use. Two surgical stapler manufacturers, Medtronic and Ethicon, expressed support for reclassifying surgical staplers for internal use to class II.

Panel Deliberations/FDA Questions:

The panel commented on whether FDA had identified a complete and accurate list of the risks to health presented by surgical staplers for internal use. Since the publication of the proposed reclassification order in April 2019, FDA had identified the potential for additional risks specifically associated with powered surgical staplers for internal use including; Complications associated with device failure/malfunction, Complications associated with use error/improper device selection and use, adverse tissue reaction and infection. The panel agreed that the list was accurate and the risk profile was consistent with class II devices. Some panel members noted that adverse tissue reaction may not be a particular risk due to the minimal patient contact duration with body tissues. Some panel members also believed that "increased risk of cancer recurrence" could be removed from the list of risks.

The Panel commented on whether, based on the available scientific evidence, there is a reasonable assurance of safety and effectiveness for surgical staplers for internal use. The Panel agreed that with proper labeling and training, surgical staplers for internal use are safe. The panel also noted that in complex situations, the user must use caution when using staplers and exercise good clinical judgment.

The panel commented and made recommendations on FDA's proposed special controls that are necessary to mitigate the risks to health and provide reasonable assurance of device safety and effectiveness including:

- Performance testing must demonstrate that the stapler, when used with compatible staples, performs as intended under anticipated conditions of use.
- Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device, as identified in the labeling, based on reading the directions for use.
- The elements of the device that may contact the patient must be demonstrated to be biocompatible.
- Performance data must demonstrate the sterility of the device.
- Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.
- Performance data must support the shelf life of the device by demonstrating continued device functionality, sterility, and package integrity over the identified shelf life.

- Labeling
- Package labels must include critical information and technical characteristics necessary for proper device selection.

The panel agreed that in general these special controls are reasonable and sufficient to support the reclassification to class II. Some members noted that biocompatibility testing may not be needed as a special control due to the limited contact duration with tissues. The panel also believed that usability and human factors testing should be required such that it focused on evaluation of the labeling rather than on the user, recommending revision of the term "labeling comprehension study" in the special controls. Some members noted that the specific language in the labeling special controls should be carefully considered and recommended collaborating with industry and professional societies on development of the labeling special controls. Some panel members felt that certain warnings in the labeling special controls, such as "establishing and maintaining proximal control of blood vessels prior to stapling" and "avoidance of use of the stapler on large blood vessels," should be removed, as they believed the labeling should allow the surgeon to exercise their own clinical judgement rather than dictating surgical practice. Further, some members of the committee believed that a registry could be helpful as part of the special controls, but there was a divergence of opinion on the need for a registry as part of device reclassification.

The panel discussed additional special controls that they believed were necessary for powered surgical staplers such as electrical safety and electromagnetic compatibility testing and software verification and validation. The committee expressed the need that powered staplers should meet these requirements. The committee also discussed unique sterility considerations regarding powered staplers.

Based upon the available scientific evidence and special controls proposed discussed, the panel unanimously recommended the reclassification of surgical staplers for internal use from Class I (general controls) to Class II (special controls).

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