

FDA NEWS RELEASE

FDA Issues Final Order and Guidance on Surgical Staplers and Staples for Internal Use

New Class II designation for surgical staplers increases safety with stronger FDA review, oversight

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Today, the U.S. Food and Drug Administration announced several actions related to surgical stapler and staple regulation and safety.

“At the heart of our public health mission is protecting the public by regulating medical devices to ensure they are safe to use,” said William Maisel, M.D., M.P.H., chief medical officer and director of the Office of Product Evaluation and Quality in FDA’s Center for Devices and Radiological Health. “The increasing reliance on surgical staplers by surgeons to perform more procedures that are minimally invasive, together with the agency’s analysis of adverse events associated with surgical staplers and implantable staples, prompted the FDA to increase regulatory oversight of these devices while continuing to educate health care providers and patients about their benefits and risks. Following our rigorous internal review and input from the public, today’s actions will increase the safe use of surgical staplers and staples as an important alternative to manual suturing.”

The agency issued a [final order reclassifying surgical staplers for internal use](https://www.federalregister.gov/public-inspection/2021-22041/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers) (<https://www.federalregister.gov/public-inspection/2021-22041/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers>) from Class I (general controls) to Class II (special controls) and requiring them to undergo premarket review. As a result, surgical staplers for internal use will be subject to more stringent regulatory requirements, including requiring premarket notification and special controls to help mitigate known risks of the device.

The FDA also issued [final guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations) ([/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations)) that describes labeling recommendations for manufacturers of surgical staplers and staples for internal use to help promote the safe and effective use of these devices by providing recommendations for developing labeling to convey information about specific risks, limitations and directions for use of the device.

An updated [Letter to Health Care Providers \(/medical-devices/letters-health-care-providers/update-safe-use-surgical-staplers-and-staples-letter-health-care-providers\)](/medical-devices/letters-health-care-providers/update-safe-use-surgical-staplers-and-staples-letter-health-care-providers) was issued along with the final order and guidance to alert health care professionals to information about the safe and effective use of surgical staplers. Through its monitoring of the use of surgical staplers and implantable staples for internal use, the FDA became aware of malfunctions and misuse associated with these devices that have resulted in serious adverse events. Today's actions will help increase the safe and effective use of surgical staplers and staples for internal use.

Surgical staplers for internal use are specialized prescription devices used during surgery to deliver compatible staples to divide, seal and connect internal tissues together and allow for healing. They are safe and effective surgical tools when used by surgeons following clear labeling with information about specific risks, limitations and directions for use of the device. Surgical staplers and staples may be indicated for use in a wide range of surgical applications, including gastrointestinal, gynecologic and thoracic surgeries. These devices may shorten surgical procedure time compared to manual suturing.

The large number of medical device reports received in recent years about serious injuries, patient deaths and device malfunctions associated with surgical staplers and staples for internal use signaled the FDA to take actions to ensure the safe and effective use of these devices. Surgical staplers and staples for internal use are used as a system; therefore, the FDA analyzed the medical device reports submitted for both surgical staplers and implantable staples to obtain a comprehensive picture of the safety profile for these devices, which found that the primary cause of adverse effects attributed to surgical staplers and staples for internal use was due to improper use of the stapler, followed by improper function of the stapler.

Today's issuance of a final order and guidance is the result of our continuous and careful evaluation of surgical staplers and staples for internal use. An earlier [Letter to Health Care Providers \(/medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers\)](/medical-devices/letters-health-care-providers/safe-use-surgical-staplers-and-staples-letter-health-care-providers) was issued in March 2019. In May 2019, the FDA convened a [public advisory committee meeting \(/advisory-committees/advisory-committee-calendar/may-30-31-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee-meeting\)](/advisory-committees/advisory-committee-calendar/may-30-31-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee-meeting) of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to discuss whether reclassifying surgical staplers for internal use from Class I to Class II would be appropriate.

Manufacturers of surgical staplers for internal use will now be required to meet these special controls outlined in the final reclassification order and be required to submit a 510(k) if they do not already have one. The FDA does not intend to enforce these requirements until 180 days after issuance of the final order.

Related Information

- [Surgical Staplers and Staples \(/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples\)](/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples)

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