FDA Statement

Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health, on new steps to help reduce risks associated with surgical staplers for internal use and implantable staples

For Immediate Release

April 23, 2019

Statement

As part of the U.S. Food and Drug Administration's mission to protect the public health, outlined in our **Medical Device Safety Action Plan (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm)**, we are committed to continuing to strengthen and modernize how we take action to address device safety issues that emerge in the post-market in a more timely and effective way. Also as part of our public health mission, it is important that we communicate with the public when we become aware of issues stemming from the use, or misuse, of medical devices.

Last month, we **alerted (/NewsEvents/Newsroom/PressAnnouncements/ucm633054.htm)** the public and health care professionals to concerns we identified—in medical device reports, recalls database and published scientific literature—regarding surgical staplers for internal use and implantable surgical staples. Surgical staplers and staples for internal use are devices used in a wide range of surgical applications, including gastrointestinal, gynecologic and thoracic surgeries to remove part of an organ, to cut through organs and tissues, and to create connections between structures. These widely used devices facilitate surgical procedures and may shorten surgical procedure time compared to manual suturing. The agency alert both warned about the risks we identified and provided recommendations to help improve the safe use of these devices given their health benefits in a surgical setting.

The alert was prompted by a large number of medical device reports associated with the use of these devices. The agency's analysis showed that from January 1, 2011 to March 31, 2018, the FDA received more than 41,000 individual adverse event reports (known as medical device reports, or MDRs), which included more than 32,000 malfunctions, more than 9,000 serious injuries and 366 patient deaths. The most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to the tissue).

Alerting the public and health care professionals was an important step, but as we shared at that time, we believe additional actions must be taken to better ensure the safe and effective use of these devices. To that end, today we are announcing three new efforts with the goal of better protecting patients from the malfunctions, injuries and deaths associated with these devices.

First, we are proposing to increase the regulatory requirements of surgical staplers for internal use by reclassifying them into a higher-risk category that requires the review and clearance of a premarket notification submission prior to marketing. The **proposed order (https://www.federalregister.gov/documents/2019/04/24/2019-08260/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers)** issued today would reclassify surgical staplers for internal use from Class I (low risk) to Class II (moderate risk) medical devices with special controls. Currently, as Class I medical devices, manufacturers of surgical staplers for internal use are not required to submit a premarket notification to the FDA prior to marketing. At the time of the device's original classification in 1988, surgical staplers had been in common use in medical practice for many years, and the FDA believed, based on the available information, that general controls were sufficient to provide reasonable assurance of the safety and effectiveness of those devices and the devices were exempt from premarket notification the following year. Reclassification of surgical staplers for internal use as a Class II device would allow the agency to require premarket review and allow us to establish special controls, such as mandatory performance testing of various mechanical features, demonstration of usability and labeling comprehension such as assessing health care professionals' ability to properly select and use the device according to the labeling, and specific labeling elements supporting the safe use of the device.

Second, today the agency also issued the draft guidance, "**Surgical Staplers and Staples for Internal Use - Labeling Recommendations (https://www.federalregister.gov/documents/2019/04/24/2019-08259/guidance-surgical-staplers-and-staples-for-internal-use--labeling-recommendations)**," to help manufacturers ensure their labeling provides adequate information for use, including relevant hazards, contraindications, and other information under which practitioners can use the device safely and for its intended purpose. The guidance recommends that manufacturers include contraindications for use, such as not using on necrotic (dead) tissue, and warnings, such as avoiding use on large blood vessels. Additionally, the guidance also recommends that the directions for use contain clear instructions, such as how to evaluate staple line formation and integrity and that the product labeling for surgical staplers and staples for internal use clearly identify key technical characteristics and performance parameters, such as the types of tissues on which the device may be used. Helping manufacturers identify appropriate information to include in their product labeling will ultimately help better protect patients by helping health care professionals better understand the appropriate use and the risks of these devices.

Finally, as announced in March, the agency intends to hold a **public meeting (https://www.federalregister.gov/documents/2019/04/24/2019-08261/meetings-general-and-plastic-surgery-devices-panel-of-the-medical-devices-advisory-committee)** of the FDA's General and Plastic Surgery Devices Panel of its Medical Devices Advisory Committee on May 30, 2019 to discuss whether the current pathway for manufacturers to market surgical staplers for internal use is appropriate and receive expert input on the proposed reclassification and draft guidance. As part of the panel meeting, we will present a comprehensive analysis of all the MDRs received for surgical staplers for internal use and implantable staples, as well as other relevant information.

The actions issued today reflect the agency's commitment to advancing policies that enhance the FDA's oversight of medical device safety. As part of the **Medical Device Safety Action Plan (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm)**, the FDA has alerted the public when safety issues are identified, as evidenced by our response to safety issues with **duodenoscopes (/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm)** and silicone injections as well as **breast implant-associated anaplastic large cell lymphoma (/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm630863.htm)**. The agency is also working with stakeholders to develop registries, including as part of the **National Evaluation System for health Technology**

(/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm), to provide more complete evidence in clinical areas to enhance the agency's ability to identify and act upon safety issues with medical devices.

Combined, we believe these steps will help better protect patients by ensuring that these devices are safe and effective for their intended use in surgeries. We remain dedicated to closely monitoring reports of adverse events associated with surgical staplers for internal use and implanted staples and will take additional action, as needed, to protect patients.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Stephanie Caccomo (mailto:stephanie.caccomo@fda.hhs.gov)
301-348-1956

Consumers

888-INFO-FDA

Related Information

- FDA: Letter to Health Care Providers: safe use of surgical staplers and staples (/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm632938.htm)
- FDA: Proposed order reclassifying surgical staplers for internal use (https://www.federalregister.gov/documents/2019/04/24/2019-08260/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers)
- FDA: Public meeting of General and Plastic Surgery Devices Panel of its Medical Devices Advisory Committee (https://www.federalregister.gov/documents/2019/04/24/2019-08261/meetings-general-and-plastic-surgery-devices-panel-of-the-medical-devices-advisory-committee)
- FDA: Draft guidance, "Surgical Staplers and Staples for Internal Use - Labeling Recommendations" (https://www.federalregister.gov/documents/2019/04/24/2019-08259/guidance-surgical-staplers-and-staples-for-internal-use--labeling-recommendations)

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