DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 16, 2015

Edwards Lifesciences LLC
Ms. Nina Brooke
Regulatory Affairs Associate III
One Edwards Way
Irvine, CA 92614

Re: K150882
Trade/Device Name: Edwards Suture Fastening System
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class I
Product Code: HCF
Dated: April 1, 2015
Received: April 2, 2015

Dear Ms. Brooke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150882

Device Name

Edwards Suture Fastening System

Indications for Use *(Describe)*

The Edwards Suture Fastening System is indicated for suture fastening in the approximation of soft tissue and prosthetic materials, including cardiovascular procedures with Edwards' surgical heart valves and annuloplasty rings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(K150882)

Submitter:	Edwards Lifesciences LLC
Contact Person*:*	Nina Brooke, Regulatory Affairs Associate III One Edwards Way Irvine, CA 92614 Phone: (949) 244-6444 Fax: (949)756-4573
Date Prepared:	April 1, 2015
Trade Name:	Edwards Suture Fastening System
Classification Name:	Instrument Ligature Passing and Knot Tying, General & Plastic Surgery Panel (21 CFR §878.4800, Product Code HCF, Class I)
Predicate Device:	K141206, Edwards ThruPort OptiClip Knotting System, Edwards Lifesciences, LLC.

Device Description

The Edwards Suture Fastening System is comprised of the fastening instrument and the fastener loader. These components interface together to deploy a nitinol fastener onto a suture and then cut the suture 5 mm proximal to the nitinol fastener. The fastening instrument has a 3 mm (0.1 inches) diameter shaft which is available in three lengths: 15 cm (5.9 inches), 22 cm (8.7 inches) and 30 cm (11.8 inches). A handle and a trigger are located at the proximal end of the instrument. By activating the trigger, the fastening instrument deploys the nitinol fastener at the intended position and cuts the suture. Each fastener loader holds one nitinol fastener which is pre-loaded in the locking tip.

Indications for Use

The Edwards Suture Fastening System is indicated for suture fastening in the approximation of soft tissue and prosthetic materials, including cardiovascular procedures with Edwards' surgical heart valves and annuloplasty rings.

Technological Characteristics

The subject device has similar technological characteristics as the predicate device, with minor design optimizations in the disposable tip, the suture snare target, the cutter assembly, and the right handle to improve manufacturability and usability.

Non-clinical Performance Data

The following nonclinical tests were completed and all results met acceptance criteria:

- Function testing

  - Knot loader suture snare tensile strength: To demonstrate that the Knot Loader suture snare can withstand forces encountered during suture loading within the Knotting Instrument.
  - Knotting system suture loading force: To establish the forces encountered during suture loading within the Knotting Instrument
  - Knotting instrument shaft stiffness: To demonstrate that the shaft of the Knotting Instrument has adequate stiffness to perform effectively within the intended use.
  - Knotting instrument weight: To demonstrate that the weight of the assembled Knotting System allows for adequate tactile feedback.
  - Dimensional interference: To demonstrate that the components of the Knotting System (including the un-deployed nitinol knot) do not exhibit dimensional interference relative to the suture prior to deployment.
  - Pinch point area: To demonstrate that the area of the exposed Knotting System pinch point is less than that of the predicate device.
  - Knotting instrument effective length: To demonstrate that the effective length of the 15cm, 22cm, and 30cm Knotting Instrument are as labeled
  - Shaft outer diameter: To demonstrate that the outer diameter of the Knotting Instrument is less than or equal to the predicate device.
  - Overall nitinol knot height: To demonstrate that the deployed nitinol knot height is less than or equal to the predicate device
  - Knot loader outer diameter: To demonstrate that the outer diameter of the Knot Loader is less than or equal to the predicate device outer diameter.
  - Knotting system deployment force: To demonstrate that the force required to fully depress the trigger and deploy a nitinol knot exceeds the weight of the Knotting System and is low enough to ensure ease of use
  - Suture tension: To demonstrate that the tension required to cut suture is less than or equal to the predicate device.
  - Knot loader disposable tip push-off force: To demonstrate that the Knot Loader locking tip will not be pushed off during the deployment of the nitinol knot.
  - Nitinol knot push-off force: To demonstrate that the Knot Loader locking tip will not be pushed off during the deployment of the nitinol knot.
  - Nitinol knot suture retention strength: To demonstrate that the nitinol knot can effectively secure the suture upon deployment when used for the intended use.
  - Knotting instrument handle strength: To demonstrate that the handle of the Knotting Instrument can withstand the force of applying suture tension and pressure onto tissue or prosthetic material.
  - Knotting instrument corrosion: To demonstrate that the Knotting Instrument can function after exposure to a simulated use environment.
  - Nitinol knot corrosion: To demonstrate that the nitinol knot does not corrode.

  - Knotting instrument durability: To demonstrate that the Knotting Instrument can function for a maximum of 25 deployment cycles.
  - Ink adherence: To demonstrate that the ink adheres to the device.
  - Nitinol knot magnetic resonance conditional testing: To substantiate the claim of magnetic resonance (MR) conditional.
  - Nitinol knot durability (600 million cycles): Demonstrate that the applicable engineering requirements for nitinol knot fatigue/durability are satisfied when used with Ethibond Excel polyester (braided) suture and 2-0 Ethicon Prolene polypropylene suture.
  - Animal studies: To demonstrate use of the device in a cardiovascular application under worse case physiological conditions (i.e., mitral bioprosthesis) using polyester and propylene suture.

- Biocompatibility testing was performed per ISO 10993-1:2009
- Sterility and sterile barrier testing
- Shelf life testing
- Packaging testing
- Design validation

Conclusion

The Edwards Suture Fastening System has similar technological characteristics as the predicate device with minor design modifications. It also has the same general indications for use as the predicate device, with additional specific indications for use in cardiovascular procedures with Edwards' surgical heart valves and annuloplasty rings, which does not raise new issues of safety or effectiveness. Nonclinical performance data have demonstrated that the subject device is substantially equivalent to the predicate device.