DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 1, 2017

Ethicon Incorporated
Mr. Hrishikesh Khatav, RAC
Senior Regulatory Affairs Specialist
U.S. Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K170767
Trade/Device Name: Stainless Steel Suture
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless Steel Suture
Regulatory Class: Class II
Product Code: GAQ
Dated: March 13, 2017
Received: March 14, 2017

Dear Mr. Khatav:

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 (DICE) 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 (DICE) 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K170767

Device Name
Stainless Steel Suture

Indications for Use *(Describe)*
Stainless Steel Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

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

Sponsor:	ETHICON, Inc. P.O. Box 151 Route 22 West Somerville, New Jersey 08876
Contact:	Hrishikesh Khatav, RAC ETHICON, Inc. P.O. Box 151 Route 22 West Somerville, New Jersey 08876 Phone: 908-218-2348 Fax: 908-218-2595 Email: hkhatav@its.jnj.com
Date of Submission:	March 13, 2017
Trade/ Proprietary Name:	Stainless Steel Suture
Common Name:	Surgical Stainless Steel Suture Suture, Non-absorbable, Steel, Monofilament and Multifilament, Sterile
Regulation Number:	21 CFR 878.4495
Regulatory Class:	II
Product Code:	GAQ
Predicate Devices:	• Surgical Stainless Steel Suture; K946173, cleared January 9, 1995; Labeling Changes for Generic Suture Types, by Ethicon, Inc., • Surgical Stainless Steel Suture; Pre-amendment Device by Ethicon, Inc.; marketed prior to May 28, 1976
Device Description:	Stainless Steel Suture is a sterile monofilament or multifilament, non-absorbable sterile surgical suture composed of 316L stainless steel. The suture is also available coated with polyethylene. Stainless Steel Suture is available in a range of gauge sizes and lengths, non-needled or attached to needles of various types and sizes. Stainless Steel Suture complies with the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Non-Absorbable Strands and the United States Pharmacopoeia (USP) for Non Absorbable Surgical Sutures. The European Pharmacopoeia recognizes units of measure Metric and Ph. Eur. sizes as equivalent which is reflected on the labeling.

Stainless Steel Suture elicits a minimal acute inflammatory reaction in tissue and is not absorbed. Implantation studies in animals show that no significant change in the retention of tensile strength of the suture occurs during the lifetime of the implantation.

Indications for Use: Stainless Steel Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

Contraindications: The use of this suture is contraindicated in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as chromium and nickel

Summary of Technological Characteristics of Proposed Device to Predicate- Labeling changes only: The principle of operation and fundamental scientific technology of the proposed device are equivalent to the predicate device. The performance modification was accomplished via testing in MRI environment and update labeling per FDA guidance "Establishing Safety and compatibility of Passive implants in the Magnetic Resonance (MR) environment" dated December 11, 2014.

A comparison between the proposed and the predicate device is given below

Table 1: Device Comparison Table

	Predicate Device	**Proposed Device**
510(k) Number	K946173	K170767
Product Code	GAQ	Same
Regulation	21 CFR 878.4495	Same
Absorbable	No	Same
Trade Name	**Surgical Stainless Steel Suture**	**Stainless Steel Suture**
Intended Use	Surgical Stainless Steel Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.	Same

Contraindication	The use of this suture is contraindicated in patients with known sensitivities or allergies to 316L stainless steel, or constituent metals such as chromium and nickel	Same
MRI Safety Information in Warnings Section	N/A	**MR Conditional** Non-clinical testing has demonstrated that Stainless Steel Suture is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: • Static magnetic field of 1.5 T or 3.0 T • Maximum spatial field gradient of 2000 gauss/cm (20 T/m) • Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg • Under the scan conditions defined, the Stainless Steel Suture is expected to produce a maximum temperature rise of less than 4.5˚C after 15 minutes of continuous scanning, using RF coils running in quadrature mode. In non-clinical testing, the image artifact caused by the Stainless Steel Suture extends approximately 20 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

How Supplied	Surgical Stainless steel sutures are available in sizes 10-0 through 7 (metric sizes 0.2 -9.0) in a variety of lengths with and without permanently attached needles in one, two and three dozen boxes.	Stainless steel sutures are available in sizes 5-0 through 7 (metric sizes 1.0 - 9.0) in a variety of lengths with and without permanently attached needles in one, two and three dozen boxes.
Color	Undyed	Same
Material	316L Stainless Steel	Same
Sterilization	Sterilized by Gamma Irradiation OR Ethylene Oxide	Same
Packaging	Surgical Stainless Steel Suture is packaged in paper folders. The folders are packaged in poly/paper and/or poly/Tyvek overwraps. The overwraps are then packed into cartons with IFU's. The cartons are then wrapped with a film or closed with a security label.	Same
U.S.P. continued Compliance - Additional Compliance to European Pharmacopeia	Surgical Stainless steel suture complies with all the requirements of the United States Pharmacopoeia U.S.P. Monograph 861, 871 and 881 for Non Absorbable Surgical Sutures	Stainless Steel Suture complies with all the requirements of the European Pharmacopoeia (Ph. Eur.) for Sterile Non-Absorbable Strands and the United States Pharmacopoeia (U.S.P.) Monograph 861, 871 and 881 for non-absorbable surgical sutures.

Performance Data: The proposed device is identical with the predicate device in respect to technological characteristics. No changes to material, construction, design or specifications. Only device labeling is updated to reflect MRI safety information, updated "How Supplied" section and additional compliance to European Pharmacopeia requirement for non-

absorbable sutures per "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Surgical Sutures".

The following Bench/Design Verification activities were performed on Stainless Steel Suture in compliance with design control requirements per 820.30 to demonstrate the continued conformance to respective FDA recognized standards for the proposed device:

Sutures – Needle Attachment per U.S.P. <871>
Tensile Strength per U.S.P. <881>
Sutures – Diameter per U.S.P. <861>

Sterilization and Biocompatibility testing
EO residual testing per AAMI/ANSI/ISO 10993-7 Biological Evaluation of Medical devices.
Pyrogenicity testing - Bacterial Endotoxin Test (BET) per ANSI/AAMI ST72:2011- Bacterial Endotoxins - Test Methods, routine monitoring and alternatives to batch testing
USP <161> Transfusion and Infusion Assemblies and Medical Devices Bacterial Endotoxin Testing (BET) as defined in USP <85>

MRI specific Testing:
Magnetic field interactions at 3-Tesla considering worst case for magnetic field interactions: Deflection Angle test for Translational Attraction and Qualitative Assessment of Torque
MRI-related Heating, 1.5-Tesla and 3.0 Tesla
MR Image Artifacts at 3-Tesla considering worst case for artifacts

Above MRI tests are in compliance with below ASTM Standards:
F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants
F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants during Magnetic Resonance Imaging
F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

Conclusions: For the purposes of determining substantial equivalence per FD&C Act Section 510(k), the proposed device is compared with the same device and design that is currently being marketed. The proposed Stainless

Steel Suture is identical to the legally marketed predicate device, Surgical Stainless Steel Suture except for labeling and trade name modifications. The modification does not change the intended use or the fundamental scientific technology. The proposed device uses the same operating principle, incorporates the same basic design and is packaged, manufactured and sterilized using the same materials and processes.

In summary, the Stainless Steel Suture described in this submission is, in our opinion, substantially equivalent to the predicate device which is legally marketed, by Ethicon, Inc. class II device with FDA product code (GAQ), regulatory definition (21 CFR 878.4495) and intended use.