510(k) SUMMARY

Sponsor: ETHICON, Inc.
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876

Contact: Elliott Jang, RAC
ETHICON, Inc.
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876
Phone: 908-541-3817
Fax: 908-218-2595
Email: ejang1@its.jnj.com

DEC 0 6 2013

Date of Submission: October 28, 2013

Proprietary Name: PROLENE™ Polypropylene Nonabsorbable Suture

Common Name: Suture, Nonabsorbable, Synthetic, Polypropylene

Regulation: 21 CFR 878.5010

Regulatory Class: II

Product Code: GAW

Predicate Devices: Labeling Changes for Generic Suture Types, by Ethicon Inc., K946173, cleared January 9, 1995

PROLENE Polypropylene Suture (Nonabsorbable Surgical Suture, U.S.P., Type B), by Ethicon Inc., NDA 16-374 approved April 16, 1969 followed by multiple supplements (converted from drug to PMA device in 1983 and then reclassified to class II device in 1990)

Device Description: PROLENE™ Polypropylene Suture (clear or pigmented) is a nonabsorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The pigmented suture is pigmented blue (with phthalocyanine blue, Color Index Number 74160) to enhance visibility.

PROLENE™ suture, also available as PROLENE™ HEMO-SEAL™ needle suture, is a needle suture combination in which the diameter of the suture swage area has been reduced to facilitate attachment of finer wire diameter needles. The diameter of the suture strand and the needle wire have been more closely aligned to reduce the degree of needle hole bleeding.

The subject device is identical to the predicate device in all aspects, including design, materials, sterilization, and packaging. The only difference between the proposed and the predicate devices is that the proposed device now meets U.S.P. for needle attachment force and that is now reflected in the labeling.

Indications for Use

PROLENE™ suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Summary of Technological Characteristics of Modified Device to Predicate

The principle of operation and fundamental scientific technology of the modified device are equivalent to the predicate device. The performance modification was accomplished via adjustments to the swaging process settings. A comparison between the proposed and the predicate device is given in Table 1 below.

Table 1: Device Comparison Table

	Proposed Device	Predicate Device
510(k) Number	TBD	K946173
Product Code	Same	GAW
Regulation	Same	21 CFR 878.5010
Absorbable	Same	No
Intended Use	Same	PROLENE suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
How Supplied	Same	The devices are available in one, two, or three dozen boxes.
Color	Same	Clear or Pigmented suture strands (pigmented blue with phthalocyanine blue, Color Index Number 74160)
Material Composition	Same	Composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin.
Sterilization	Same	Sterilized by Ethylene Oxide
Packaging	Same	Plastic tray or paper folder placed within sealed Tyvek –

		copolymer overwrap. Individual overwrap pouch packages placed within paperboard carton.
U.S.P. requirements	Meets U.S.P. Monograph – except for Diameter for 7-0 PROLENE	Meets U.S.P. Monograph – except for Diameter for 7-0 PROLENE, and except for Needle Attachment for HEMO-SEAL.

Performance Data

Design Verification Testing (U.S.P. <871> – Sutures – Needle Attachment; U.S.P. <881> – Tensile Strength; U.S.P. <861> – Sutures – Diameter) was conducted to demonstrate the performance of the modified PROLENE™ HEMOSEAL™ Polypropylene Nonabsorbable Suture.

Conclusions

Based on the similarities to the predicate device identified in this submission as well as the outcome of design verification, and that the devices have the same intended use, the same fundamental technology, and the same principle of operation, we conclude that the modified device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Ethicon, Incorporated
Mr. Elliott Jang, RAC
Manager, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K133356
Trade/Device Name: PROLENE™ POLYPROPYLENE NONABSORBABLE SUTURE
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: November 18, 2013
Received: November 19, 2013

Dear Mr. Jang:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133356

Device Name
PROLENE™ POLYPROPYLENE NONABSORBABLE SUTURE

Indications for Use *(Describe)*

PROLENE™ suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S