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

August 13, 2015

Ethicon Incorporated a Johnson & Johnson company
Ms. Donna Marshall
Manager, Regulatory Affairs
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K151200
Trade/Device Name: STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/l-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: July 9, 2015
Received: July 10, 2015

Dear Ms. Marshall:

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" (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 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,

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)*

K151200

Device Name

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device

Indications for Use *(Describe)*

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device are indicated for soft tissue approximation where use of an absorbable suture is appropriate.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon Inc. a Johnson & Johnson company
P.O. Box 151
Route 22 West
Somerville, NJ 08876-0151
USA

Contact Person: Donna Marshall
Manager, Regulatory Affairs
Ethicon, Inc. a Johnson & Johnson company
Ph: (908) 541-3990
Fax: (908) 218-2595
e-mail: dmarsha2@its.jnj.com

Date Prepared: August 12, 2015

Device Trade Name: STRATAFIX™ Spiral MONOCRYL™
Knotless Tissue Control Device
and
STRATAFIX™ Spiral MONOCRYL™ Plus
Knotless Tissue Control Device

Device Common Name: Suture, Surgical, Absorbable, Polyglcolic Acid

Class: II

Classification Name: Suture, Absorbable, Synthetic, Polyglcolic Acid
(21 CFR 878.4493)

Product Code: GAM

Predicate Device	**510(k) Number**
MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture	K050845
Quill™ MONODERM™ Knotless Tissue Closure Device, Variable Loop Design	K141778 K123836 K123409

Device Description:

The STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is a monofilament, synthetic absorbable device prepared from a copolymer of glycolide and ε-caprolactone. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX™ Spiral MONOCRYL™ Device is designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end. The STRATAFIX™ Spiral MONOCRYL™ Device barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral MONOCRYL™ Device reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduces their effective strengths. For this reason, the strength of the STRATAFIX™ Spiral MONOCRYL™ Device can be compared to USP knot strength of non-barbed sutures. USP designations for diameter are used to describe the STRATAFIX™ Spiral MONOCRYL™ Device suture material after barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm.

The STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device is an antibacterial monofilament, synthetic absorbable device prepared from a copolymer of glycolide and ε-caprolactone. The device contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 µg/m. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device, Variable Loop Design consists of barbed suture material, armed with a surgical needle on one end and a fixation loop at the opposite end. The STRATAFIX™ Spiral MONOCRYL™ Plus Device is designed to anchor with a closed loop at one end and a unidirectional barbed section on the other end. The STRATAFIX™ Spiral MONOCRYL™ Plus Device barbs are oriented in one direction to allow tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral MONOCRYL™ Plus Device reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduces their effective strengths. For this reason, the strength of the STRATAFIX™ Spiral MONOCRYL™ *Plus* Device can be compared to USP knot strength of non-barbed sutures. USP designations for diameter are used to describe the STRATAFIX™ Spiral MONOCRYL™ Plus Device suture material after barbing, except for minor variation in suture diameter with a maximum overage of 0.1 mm.

Indications for Use:

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

Performance Data:

Non-clinical laboratory performance testing was performed demonstrating that STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices conforms to the current USP Monograph for absorbable surgical sutures, except for diameter. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. In addition, bench and animal testing was provided showing that the device performed as intended and as claimed.

Below you will find a list of non-clinical performance data completed for the STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices:

Bench Testing	**Biocompatiblity**	***In-vitro/In-vivo***
Suture Diameter	Intramuscular Implantation	Breaking Strength Retention
Tensile Strength	Subcutaneous Implantation	Wound Holding Strength
Needle Attachment	Irritation (Intracutaneous Reactivity)	Wound Healing
	Pyrogenicity	Bacterial Colonization

Substantial Equivalence:

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices have the same intended use and similar indications for use as the predicate devices. The technological differences between the subject devices, STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device and the predicate devices raise no new questions of safety or effectiveness. STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Devices and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Devices met all testing criteria to demonstrate substantial equivalence to the predicates devices. The following table compares the subject devices to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Traditional 510(k)
STRATAFIX™ Spiral MONOCRYL™ and
STRATAFIX™ Spiral MONOCRYL™ PLUS
Knotless Tissue Control Device
Ethicon, Inc.

Comparison Table:

Comparison of Subject Device Characteristics to Predicate Devices

Characteristic	Subject Device: STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device	Subject Device: STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device	Predicate Device: MONOCRYL Plus Antibacterial Sutures (K050845)	Predicate Device: Quill™ Knotless Tissue Closure Device (Variable Loop Design) Comprised of MONODERM™ (PGA-PCL) (K141778, K123836, K123409)
Indications for Use	STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.	STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.	MONOCRYL Plus Antibacterial sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.	Quill™ MONODERM device is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.
Technological means for achieving intended use	Monofilament strand to approximate tissue anchored without the need to tie surgical knots.	Monofilament strand to approximate tissue anchored without the need to tie surgical knots.	Monofilament strand to approximate tissue anchored with surgical knots.	Monofilament strand to approximate tissue anchored without the need to tie surgical knots.
Absorbable/ Suture Material	MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone	MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone	MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone	Monoderm™ (PGA-PCL) – composed of a copolymer of glycolide and e-caprolactone
Suture Design	Monofilament strand. Single armed, unidirectional barbs made by cutting into the core of the suture strand. Contains adjustable loop.	Monofilament strand. Single armed, unidirectional barbs made by cutting into the core of the suture strand. Contains adjustable loop.	Monofilament strand	Uni-directional barbs along the long axis of the monofilament
Colorant (if dyed)	Undyed	Undyed	Undyed or Dyed (D&C Violet No.2)	Undyed or Violet (D&C Violet No.2)
USP Suture Size	2-0 through 4-0	2-0 through 4-0	0, 1, 2-0 through 6-0	0, 2-0 through 5-0

Traditional 510(k)
STRATAFIX™ Spiral MONOCRYL™ and
STRATAFIX™ Spiral MONOCRYL™ PLUS
Knotless Tissue Control Device
Ethicon, Inc.

Tensile Strength	Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of the same size equivalent	Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of the same size equivalent	Meets USP requirement for Synthetic Absorbable Sutures	Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of one size smaller equivalent
Needle Pull-Off	Meets USP requirements	Meets USP requirements	Meets USP requirements	Meets USP requirements
Antibacterial Agent	Not Applicable	Irgacare MP (Triclosan)	Irgacare MP (Triclosan)	Not Applicable
Maximum Level of Antibacterial Agent	Not Applicable	≤ 2360 µg/m	≤ 2360 µg/m	Not Applicable
Approximate % Breaking Strength Retention (BSR)	62% @ 7 days 27% @ 14 days	62% @ 7 days 27% @ 14 days	50 – 60% @ 7 days 20 – 30% @ 14 days (undyed)	62% @ 7 days 27% @ 14 days
Absorption Profile	Essentially absorbed by 91days post-implantation	Essentially absorbed by 91days post-implantation	Essentially complete between 91 and 119 days	Essentially complete between 90 and 120 days
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Single Use?	Yes	Yes	Yes	Yes
Packaging Configuration	Plastic tray with paper lid (contains the suture) placed within foil pouch (sterile barrier). Sterile foil pouches are packaged in a sales carton.	Plastic tray with paper lid or paper folder (contains the suture) placed within foil pouch (sterile barrier). Sterile foil pouches are packaged in a sales carton.	Paper folder or plastic tray within a foil pouch. Pouches placed within sales carton	Device wound onto inner support card, within a Single Barrier Foil Pouch

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device and STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device have been shown to be appropriate for its intended use and are considered to be substantially equivalent to the predicate devices.

* *Trademark*
IRGACARE®* MP (triclosan) “Registered Trademark of BASF Group”