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” (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,

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
Indications for Use

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.

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ETHICON, INC.  
a Johnson & Johnson company

510(k) Summary

Submitter: Ethicon Inc. a Johnson & Johnson company  
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USA

Contact Person: Donna Marshall  
Manager, Regulatory Affairs  
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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

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>510(k) Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>MONOCRYL™ Plus Antibacterial (poliglecaprone 25) Suture</td>
<td>K050845</td>
</tr>
<tr>
<td>Quill™ MONODERM™ Knotless Tissue Closure Device, Variable Loop Design</td>
<td>K141778, K123836, K123409</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Bench Testing</th>
<th>Biocompatibility</th>
<th>In-vitro/In-vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture Diameter</td>
<td>Intramuscular Implantation</td>
<td>Breaking Strength Retention</td>
</tr>
<tr>
<td>Tensile Strength</td>
<td>Subcutaneous Implantation</td>
<td>Wound Holding Strength</td>
</tr>
<tr>
<td>Needle Attachment</td>
<td>Irritation (Intracutaneous Reactivity)</td>
<td>Wound Healing</td>
</tr>
<tr>
<td></td>
<td>Pyrogenicity</td>
<td>Bacterial Colonization</td>
</tr>
</tbody>
</table>

**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.
## Comparison Table:

Comparison of Subject Device Characteristics to Predicate Devices

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.</td>
<td>STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.</td>
<td>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.</td>
<td>Quill™ MONODERM device is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.</td>
</tr>
<tr>
<td><strong>Technological means for achieving intended use</strong></td>
<td>Monofilament strand to approximate tissue anchored without the need to tie surgical knots.</td>
<td>Monofilament strand to approximate tissue anchored without the need to tie surgical knots.</td>
<td>Monofilament strand to approximate tissue anchored with surgical knots.</td>
<td>Monofilament strand to approximate tissue anchored without the need to tie surgical knots.</td>
</tr>
<tr>
<td><strong>Absorbable/ Suture Material</strong></td>
<td>MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone</td>
<td>MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone</td>
<td>MONOCRYL is composed of a copolymer of glycolide and ε-caprolactone</td>
<td>Monoderm™ (PGA-PCL) – composed of a copolymer of glycolide and ε-caprolactone</td>
</tr>
<tr>
<td><strong>Suture Design</strong></td>
<td>Monofilament strand. Single armed, unidirectional barbs made by cutting into the core of the suture strand. Contains adjustable loop.</td>
<td>Monofilament strand. Single armed, unidirectional barbs made by cutting into the core of the suture strand. Contains adjustable loop.</td>
<td>Monofilament strand</td>
<td>Uni-directional barbs along the long axis of the monofilament</td>
</tr>
<tr>
<td><strong>Colorant (if dyed)</strong></td>
<td>Undyed</td>
<td>Undyed</td>
<td>Undyed or Dyed (D&amp;C Violet No.2)</td>
<td>Undyed or Violet (D&amp;C Violet No.2)</td>
</tr>
<tr>
<td><strong>USP Suture Size</strong></td>
<td>2-0 through 4-0</td>
<td>2-0 through 4-0</td>
<td>0, 1, 2-0 through 6-0</td>
<td>0, 2-0 through 5-0</td>
</tr>
<tr>
<td><strong>Tensile Strength</strong></td>
<td>Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of the same size equivalent</td>
<td>Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of the same size equivalent</td>
<td>Meets USP requirement for Synthetic Absorbable Sutures of one size smaller equivalent</td>
<td>Straight Tensile meets USP Knot Tensile requirements for Synthetic Absorbable Sutures of the same size equivalent</td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Needle Pull-Off</strong></td>
<td>Meets USP requirements</td>
<td>Meets USP requirements</td>
<td>Meets USP requirements</td>
<td>Meets USP requirements</td>
</tr>
<tr>
<td><strong>Antibacterial Agent</strong></td>
<td>Not Applicable</td>
<td>Irgacare MP (Triclosan)</td>
<td>Irgacare MP (Triclosan)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Maximum Level of Antibacterial Agent</strong></td>
<td>Not Applicable</td>
<td>≤ 2360 µg/m</td>
<td>≤ 2360 µg/m</td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Approximate % Breaking Strength Retention (BSR)</strong></td>
<td>62% @ 7 days  27% @ 14 days</td>
<td>62% @ 7 days  27% @ 14 days</td>
<td>50 – 60% @ 7 days  20 – 30% @ 14 days (undyed)</td>
<td>62% @ 7 days  27% @ 14 days</td>
</tr>
<tr>
<td><strong>Absorption Profile</strong></td>
<td>Essentially absorbed by 91 days post-implantation</td>
<td>Essentially absorbed by 91 days post-implantation</td>
<td>Essentially complete between 91 and 119 days</td>
<td>Essentially complete between 90 and 120 days</td>
</tr>
<tr>
<td><strong>Sterilization Method</strong></td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
</tr>
<tr>
<td><strong>Single Use?</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Packaging Configuration</strong></td>
<td>Plastic tray with paper lid (contains the suture) placed within foil pouch (sterile barrier). Sterile foil pouches are packaged in a sales carton.</td>
<td>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.</td>
<td>Paper folder or plastic tray within a foil pouch. Pouches placed within sales carton.</td>
<td>Device wound onto inner support card, within a Single Barrier Foil Pouch</td>
</tr>
</tbody>
</table>
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”