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

July 2, 2015

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

Re: K150670
Trade/Device Name: STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: June 4, 2015
Received: June 5, 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)*
K150670

Device Name

STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device

Indications for Use *(Describe)*

STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device is 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.

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ETHICON, INC.
a Johnson & Johnson company

510(k) Summary

Submitter:
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USA

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Date Prepared: March 13, 2015

Device Trade Name: STRATAFIX™ Spiral PDS™ Plus
Knotless Tissue Control Device

Device Common Name: Suture, Surgical, Absorbable, Polydioxanone

Class: II

Classification Name: Absorbable Polydioxanone Surgical Suture (21 CFR 878.4840)

Product Code: NEW

Predicate Device	**510(k) Number**
PDS™ Plus Antibacterial (polydioxanone) Suture	K061037
Quill™ PDO Knotless Tissue Closure Device, Variable Loop (polydioxanone)	K123877 K113744 K132268
Quill™ PDO Knotless Tissue Closure Device	K120827

Device Description:

The STRATAFIX™ Spiral PDS™ *Plus* Device is an antibacterial monofilament, synthetic absorbable device consisting of dyed (violet) polyester, poly(p-dioxanone), the empirical molecular formula of which is $(C_4H_6O_3)_X$. The device contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 µg/m. The pigment for the violet dye is D&C Violet No. 2. Polydioxanone polymer has been found to be nonallergenic, nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral PDS™ *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 PDS™ *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 PDS™ *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 PDS™ *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 strength. For this reason, the strength of the STRATAFIX™ Spiral PDS™ *Plus* Device can be compared to USP knot strength of non-barbed sutures. Additionally, USP designations for diameter are used to describe the STRATAFIX™ Spiral PDS™ *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 PDS™ 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 PDS™ Plus Knotless Tissue Control Device 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.

Summary of Technological Characteristics and Performance Testing:

The STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device has similar technological characteristics as the predicate devices. Like the currently marketed devices, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device is a sterile, monofilament synthetic absorbable suture intended for the approximation of soft tissue that conforms to the

USP Monograph for absorbable surgical sutures, except for diameter. Similar to the currently marketed PDS Plus suture, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device will be available as a suture product with IRGACARE ®* MP, an antibacterial agent.

Substantial Equivalence:

STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device has the same intended use and similar indications for use as the predicate devices. The technological differences between the subject device, STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device and the predicate devices raise no new questions of safety or effectiveness. STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device met all testing criteria to demonstrate substantial equivalence to the predicates devices.

Conclusion:

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

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