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**5 510(K) SUMMARY**

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**Applicant:** Ethicon Inc. FEB 5 2013  
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Somerville, NJ 08876  
USA  
Phone: +1-908-218-2256  
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**Contact Person:** Susan Lin

**Date:** September 28, 2012

**Trade Device Name:** ETHICON SECURESTRAP™ *Open* Absorbable Strap Fixation Device

**Common Device Name:** Implantable Staple

**Classification:** Class II, 21CFR 878.4750, Product Code: GDW

**Predicate Devices:** ETHICON SECURESTRAP™ 5 mm Absorbable Strap Fixation Device (K093845)

**Manufacturer:** Ethicon LLC  
Guaynabo, Puerto Rico 00969  
USA

**Description of the Device Subject to Premarket Notification:**

The ETHICON SECURESTRAP™ *Open* Absorbable Strap Fixation Device is a trigger-squeeze mechanical device with a curved cannula, pre-loaded with 20 absorbable straps. The ETHICON SECURESTRAP™ Fixation Device straps are made of a blend of polydioxanone dyed with D&C Violet No. 2 and a L(-)-Lactide/glycolide copolymer. The inserted length of the strap is 6.7 mm.

**Indications for Use:**

The ETHICON SECURESTRAP™ *Open* Absorbable Strap Fixation Device is intended for fixation of prosthetic material to soft tissues in open surgical procedures, such as hernia repairs.

## **Summary of Technological Characteristics of New Device to Predicate Devices:**

The principle of operation and fundamental scientific technology of the proposed device are equivalent to the predicate device. Both the ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device and the ETHICON SECURESTRAP™ 5 mm Absorbable Strap Fixation Device function in the same manner – they are designed for fixation of prosthetic material to soft tissues in surgical procedures, such as hernia repairs. They perform this function by delivering absorbable straps into the tissue of the abdominal wall. The strap delivery system in the proposed device is specifically designed for open surgical repair procedures and consists of a newly designed ergonomic handle and trigger, modified lockout counter, modified mesh positioning tip, and includes 20 pre-loaded absorbable straps.

## **Performance Data:**

The ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device underwent an extensive safety and performance testing program, including bench and animal testing, to support that the ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device meets the device requirements as defined in user specifications, performs as intended, and is substantially equivalent to the predicate device. The tests conducted include:

- Biocompatibility testing in accordance to the tests recommended in the ISO 10993-1 standard
- Bench top physical/performance measurements including mesh fixation force and mesh compatibility testing in animal tissue model

## **Conclusion:**

The ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device has the same intended use, fundamental scientific technology, and principles of operation as its predicate device. Performance data demonstrates that the device is as safe and as effective as the predicate device for the intended use. The minor delivery system differences between the ETHICON SECURESTRAP™ Open Absorbable Strap Fixation Device and the ETHICON SECURESTRAP™ Fixation Device raise no new issues of safety or effectiveness as verified by performance data.

Thus we conclude that the proposed device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.



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

Ethicon, Incorporated  
% Ms. Susan Lin  
Manager, Regulatory Affairs  
Route 22 West  
P.O. Box 151  
Somerville, New Jersey 08876-0151

February 5, 2013

Re: K123114  
Trade/Device Name: ETHICON SECURESTRAP™ Open Absorbable Strap Fixation  
Device  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: Class II  
Product Code: GDW  
Dated: January 14, 2013  
Received: January 16, 2013

Dear Ms. Lin:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

**Peter D. Rumm -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4 INDICATIONS FOR USE STATEMENT

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510(k) No (if known): K123114

Device Name: ETHICON SECURESTRAP™ *Open* Absorbable Strap Fixation Device

**Indications for Use:**

The ETHICON SECURESTRAP™ *Open* Absorbable Strap Fixation Device is intended for fixation of prosthetic material to soft tissues in open surgical procedures, such as hernia repairs.

Prescription Use √  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

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(Division Sign-Off)  
Division of Surgical Devices  
510(k) Number: K123114