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510(k) Summary

Entuit™ Secure Gastrointestinal Suture Anchor Set
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set
21 CFR §876.5010
Date Prepared: June 19, 2013

Submitted By:

Applicant: Cook Incorporated
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P.O. Box 489
Bloomington, IN 47402

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Contact: Erum B. Nasir
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OCT 07 2013

Device Information:

Trade Name: Entuit™ Secure Gastrointestinal Suture Anchor Set
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set
Common Name: Suture Anchor Set
Proposed Classification: II
Regulation: 21 CFR §876.5010
Product Code: FGE

Intended Use:

The Entuit™ Secure Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.

The Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.

Predicate Devices:

The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set are substantially equivalent to the Connex Gastrointestinal Suture Anchor Set, subject of Premarket Notification K090133, manufactured by Cook Incorporated and cleared for commercial distribution on January 20, 2009.

Comparison to Predicate Device:

The components of the predicate, Connex Gastrointestinal Suture Anchor Set and the proposed devices, the Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set are identical, and consist of the wire guides, introducer needles, suture, and the suture anchors.

Moreover, the proposed devices are substantially equivalent to the predicate in terms of intended use, principles of operation, insertion method, anatomical location, and method of sterilization.

A difference in the technological characteristic of the predicate device and the proposed devices is in the suture anchoring mechanism. The predicate, Connex Gastrointestinal Suture Anchor Set maintains the retention of the suture anchor to the abdominal wall by an anchoring mechanism which consists of disks and crimp beads.

The suture retention mechanism of the Entuit™ Secure Gastrointestinal Suture Anchor Set maintains the retention of the suture anchor to the abdominal wall by passing the suture through an extension spring inside the suture retention mechanism housing. Whereas, the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set maintains the retention of the suture anchor to the abdominal wall by threading the suture through the retention housing with the suture held in place by a compression jaw and spring. The adjustable tab is removable and can be used to adjust the suture.

Device Description:

The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set consist of 2 or 3 introducer needles with pre-loaded suture anchors and a wire guide. A notch is located on the distal tip of the introducer needle. The coil of the anchor is placed in the notch prior to placement. The proximal end of the suture anchor contains the suture retention mechanism.

The retention mechanism of the Entuit Secure Gastrointestinal Suture Anchor consists of an extension spring which is glued on the proximal end within a suture retention housing. The suture is threaded through the coils of the extension spring. When the suture retention mechanism is pushed towards the anchor, tension is applied to the spring, which causes the coils of the spring to open. This allows the suture to slide through the spring and allows the retention mechanism to slide along the suture. When the retention mechanism is pulled away from the

anchor, the coils of the spring compress and clamp down on the suture. This does not allow the suture to slide through the spring and maintains tension on the suture anchor.

The adjustable suture retention mechanism of the Entuit Secure Adjustable Gastrointestinal Suture Anchor Set consists of a suture retention housing, a compression spring, a compression jaw, and a removable adjustable tab. The suture is threaded through the suture retention housing and held in place by the compression jaws and the compression spring. The adjustable tab must be compressed for the suture to be adjusted. When the adjustable tab is compressed, the spring and compression jaws do not contact the suture. This allows the suture retention mechanism to slide along the suture. Once the suture retention mechanism is in place, the compression jaws will maintain tension on the suture anchor, and the adjustable tab can be removed.

Both of the proposed devices are supplied sterile and are intended for one-time use.

Comparison of Technological Characteristics:

The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set were subjected to the following tests to assure reliable design and performance under the specified testing parameters:

1. Tensile Testing - Testing shows that the tensile strength during proper clinical use of the devices should be capable of maintaining the proper tensile force requirements to anchor the anterior wall of the stomach to the abdominal wall. Testing demonstrated that the device met all predetermined acceptance criteria.
2. Fatigue Testing - Testing shows that under normal clinical use of the devices there should be no mechanism or suture failure.
3. Biocompatibility Testing - Testing (i.e., cytotoxicity, sensitization, intracutaneous and systemic toxicity, and pyrogenicity) shows that the devices are biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

The Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set was also subjected to torque testing. Testing shows that the device can withstand the torsional forces seen during proper clinical use.

Testing demonstrated that the Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set met all predetermined acceptance criteria.

Conclusions Drawn from the Tests:

The results of these tests provide reasonable assurance that the Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set are as safe and effective as the predicate device and support a determination of substantial equivalence.

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

October 7, 2013

Cook, Inc.
% Erum B. Nasir
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K131201
Trade/Device Name: Entuit™ Secure Gastrointestinal Suture Anchor Set
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 30, 2013
Received: September 3, 2013

Dear Erum B. Nasir,

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131201

Device Name: Entuit™ Secure Gastrointestinal Suture Anchor Set
Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set

Indications for Use:

The Entuit™ Secure Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.

The Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set is intended for anchoring the anterior wall of the stomach to the abdominal wall prior to introduction of interventional catheters.

Prescription Use X OR Over–the-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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