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

September 30, 2015

Cook Incorporated
Erum B. Nasir, MS
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K152524
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: September 2, 2015
Received: September 3, 2015

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 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,

Joyce M. Whang -S

for 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

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)*

K152524

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

Indications for Use *(Describe)*

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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.***

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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."*

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## 10.0 510(k) SUMMARY

**Entuit™ Secure Gastrointestinal Suture Anchor Set**
**Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set**
**21 CFR §876.5010**
**Date Prepared: 2 September 2015**

**Submitted By:**

| | |
|---|---|
| Applicant: | Cook Incorporated |
| Contact: | Erum B. Nasir, MS |
| Applicant Address: | Cook Incorporated<br>750 Daniels Way<br>Bloomington, IN 47404 |
| Contact Phone Number: | (812) 335-3575 x102607 |
| Contact Fax Number: | (812) 332-0281 |

**Device Information:**

| | |
|---|---|
| Trade Name: | Entuit™ Secure Gastrointestinal Suture Anchor Set<br>Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set |
| Common Name: | Biliary Catheter and Accessories |
| Classification Name: | Catheter, Biliary, Diagnostic |
| Regulation: | 21 CFR §876.5010 |
| Product Code | FGE |

**Predicate Device:**

- K131201, Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set

**Device Description:**

The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set are used in gastropexy procedures. The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set consist of 2 or 3 stainless steel silicone coated introducer needles with pre-loaded suture anchors and a wire guide. An additional sterile prepackaged red adjustable plunger is packaged with the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set.

The Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set are supplied sterile and are intended for one-time use.

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**Indications for Use:**

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

**Comparison to Predicates:**

It has been demonstrated that the subject devices are substantially equivalent to the predicate devices, the Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set (K131201), in that these devices have similar designs, methods of construction and operation, and indications for use. A coating of silicone lubricant has been added to the outer surface of the stainless steel introducer needles, a component of the subject devices. The safety and effectiveness of the modification is supported by testing.

**Technological Characteristics:**

The following tests were performed to demonstrate that the subject devices met applicable design and performance requirements and support a determination of substantial equivalence.

- Biocompatibility Testing – Testing showed that the devices met the requirements of ISO 10993-1.
- Insertion Force Testing – Testing showed that applying silicone to the outer surface of the needle reduced the insertion force to less than 1.5 N. The acceptance criterion was met.
- Ease of Insertion Testing – Testing showed that needles coated with silicone lubricant are easier to advance. The acceptance criterion was met.

**Conclusion:**

The results of this testing support a conclusion that the proposed devices met the design input requirements based on the intended use and these devices do not raise new questions of safety or effectiveness as compared to the predicate and are therefore substantially equivalent to the predicate devices, the Entuit™ Secure Gastrointestinal Suture Anchor Set and the Entuit™ Secure Adjustable Gastrointestinal Suture Anchor Set (K131201).