September 14, 2017

Cook Incorporated
Erum B. Nasir
Regulatory Affairs Team Lead
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K170323
Trade/Device Name: Entuit Start Initial Placement Gastrostomy Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KGC
Dated: August 8, 2017
Received: August 9, 2017

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 (DICE) 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 (DICE) 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,

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
**Indications for Use**

510(k) Number *(if known)*
K170323

Device Name
Entuit Start Initial Placement Gastrostomy Set

Indications for Use *(Describe)*
The Entuit Start Initial Placement Gastrostomy Set is intended to assist the physician with the initial placement of feeding tubes while performing a gastrostomy in adult patients only.

Type of Use *(Select one or both, as applicable)*
- [x] 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
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Office of Chief Information Officer  
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PRASStaff@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.*
1.0 510(k) SUMMARY

Entuit™ Start Initial Placement Gastrostomy Set
As required by 21 CFR §807.92
Date Prepared: September 14, 2017

Submitted By:
Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact: Erum B. Nasir
Email: RegSubmissions@CookMedical.com
Contact Phone Number: (812) 335-3575 x102607
Contact Fax Number: (812) 332-0281

Device Information:
Trade Name: Entuit™ Start Initial Placement Gastrostomy Set
Common Name: Gastrointestinal tube and accessories
Classification Name: Tube, Gastro-Enterostomy
Regulation: 21 CFR §876.5980
Product Code: KGC
Device Class: II
Classification Panel: Gastroenterology/Urology

Predicate Device:
The Entuit™ Start Initial Placement Gastrostomy Set is substantially equivalent to the
Kimberly-Clark Introducer Kits (K080253), cleared by FDA on February 26, 2008.

Device Description:
The Entuit™ Start Initial Placement Gastrostomy Set includes a heavy duty stainless steel
polytetrafluoroethylene (PTFE) coated Amplatz extra stiff wire guide, dilators, and one or
more Peel-Away® Introducers. Depending upon set specifications, two or three dilators
may be included. The set also includes an entry access needle, scalpel, syringe, and gauze. The Entuit Start Initial Placement Gastrostomy Set is sterilized by ethylene oxide and intended for one-time use.

**Intended Use:**
The Entuit™ Start Initial Placement Gastrostomy Set is intended to assist the physician with the initial placement of feeding tubes while performing a gastrostomy in adult patients only.

**Comparison to Predicate Device:**
The Entuit™ Start Initial Placement Gastrostomy Set and the predicate device, the Kimberly-Clark Introducer Kits (K080253), are substantially equivalent in that these devices are similar in intended use and principles of operation. The differences between the subject device and the predicate device, including the materials, dimensions, and components within the sets, do not raise any new issues of safety and effectiveness. The substantial equivalence comparison of the subject device to the predicate device is provided in the table below.

<table>
<thead>
<tr>
<th></th>
<th>Kimberly-Clark Introducer Kits (K080253)</th>
<th>Entuit™ Start Initial Placement Gastrostomy Set (Subject of this submission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Number</td>
<td>21 CFR §876.5980</td>
<td>Identical</td>
</tr>
<tr>
<td>Product Code</td>
<td>KGC</td>
<td>Identical</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II</td>
<td>Identical</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The Kimberly-Clark Introducer Kits are intended to facilitate primary placement of Kimberly-Clark, Kimberly-Clark MIC and Kimberly-Clark MIC-KEY brand of gastrostomy feeding tubes.</td>
<td>The Entuit Start Initial Placement Gastrostomy Set is intended to assist the physician with the initial placement of feeding tubes while performing a gastrostomy in adult patients only.</td>
</tr>
<tr>
<td>Wire Guide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diameter (inch)</td>
<td>Unknown</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Length (cm)</td>
<td>Unknown</td>
<td>100</td>
</tr>
<tr>
<td>Dilator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diameter (Fr)</td>
<td>Not included</td>
<td>12, 14, 16, 18, 20, 22, 24</td>
</tr>
<tr>
<td>Length (cm)</td>
<td>Not included</td>
<td>20</td>
</tr>
<tr>
<td>Shaft Material</td>
<td>Not included</td>
<td>Polyethylene (12 Fr Dilator), Polyvinyl chloride (14 - 24 Fr dilators)</td>
</tr>
<tr>
<td>Hydrophilic Coating</td>
<td>Unknown</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Technical Characteristics:

The subject Entuit™ Start Initial Placement Gastrostomy Set was subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

- Compatibility - (Peel away sheath and Gastrostomy Catheter, Dilator and Wire Guide, Needle and Wire Guide)
- Wire Guide Tensile
- Wire Guide Corrosion
- Wire Guide Flex
- Wire Guide Fracture
- Dilator Shaft Tensile
- Dilator Hub-to-Shaft Tensile

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<table>
<thead>
<tr>
<th>Peel-Away Introducer (Sheath and Dilator)</th>
<th>Kimberley-Clark Introducer Kits (K080253)</th>
<th>Entuit™ Start Initial Placement Gastrostomy Set (Subject of this submission)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (Fr)</td>
<td>16, 18, 20, 22, 24*</td>
<td>16, 18, 20, 22, 26</td>
</tr>
<tr>
<td>Sheath Material</td>
<td>NA</td>
<td>Polytetrafluoroethylene (PTFE)</td>
</tr>
<tr>
<td>Sheath Length (cm)</td>
<td>N/A</td>
<td>15.5 (for 16 &amp; 18 Fr)</td>
</tr>
<tr>
<td>Dilator Shaft Material</td>
<td>Unknown</td>
<td>Polyvinyl chloride</td>
</tr>
<tr>
<td>Dilator Length (cm)</td>
<td>N/A</td>
<td>20</td>
</tr>
<tr>
<td>Compatible Gastrostomy tube size (Fr)</td>
<td>12, 14, 16, 18, 20</td>
<td>12, 14, 16, 18, 20, 22, 24</td>
</tr>
<tr>
<td>Gastrointestinal Anchor Set</td>
<td>Gastrointestinal Anchor Set with Saf-T-Pexy* T-Fasteners</td>
<td>Not included – FDA cleared (K131201 and K152524), sold separately</td>
</tr>
<tr>
<td>Accessory components</td>
<td>18 g Safety introducer needle Safety Scalpel No.11 Blade 12 ml syringe Hemostat Stoma Measuring Device</td>
<td>18 g entry access needle Safety Scalpel No.11 Blade 6cc syringe Gauze**</td>
</tr>
<tr>
<td>Packaging</td>
<td>Unknown</td>
<td>Tray: Polyethylene terephthalate Pouch: Polyethylene, Tyvek Spiral Holder: Polyethylene</td>
</tr>
<tr>
<td>Sterility Assurance Level (SAL)</td>
<td>Unknown</td>
<td>10⁻⁶</td>
</tr>
</tbody>
</table>

*Device includes serial dilators with varying size increments.

**Stoma measuring device is cleared under K130674 and is sold separately.
• Peel-Away Introducer Shaft Tensile
• Peel-Away Introducer Knob-to-Shaft Tensile
• Peel Force Testing
• Radiopacity Testing
• Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, and acute systemic toxicity were performed to ensure the biocompatibility of the subject device set.

**Conclusion:**
The results of these tests show that the Entuit™ Start Initial Placement Gastrostomy Set met the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and support a determination of substantial equivalence.