May 1, 2018

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

Re: K173035
Trade/Device Name: Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter and the Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, Multipurpose Drainage Catheters and Sets
Regulation Number: 21 CFR § 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE, LJE, GBO
Dated: March 26, 2018
Received: March 27, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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)

K173035

Device Name

Gordon Large-Bore Curved Drainage Catheter
Nephrostomy Pigtail Drainage Catheter and the Percutaneous Nephrostomy Set
Pigtail Drainage Catheter Needle Set

Indications for Use (Describe)

The Gordon Large-Bore Curved Drainage Catheter is intended for abscess drainage.

The Nephrostomy Pigtail Drainage Catheter and Percutaneous Nephrostomy Set are intended for external urine drainage from the renal pelvis.

The Pigtail Drainage Catheter Needle Set is intended for percutaneous external drainage in multiple applications (e.g., nephrostomy, abscess drainage and other abdominal cavity drainage procedures).

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.

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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.”
Indications for Use

510(k) Number (if known)
K173035

Device Name
Multipurpose Drainage Catheters and Sets

Indications for Use (Describe)
The Multipurpose Drainage Catheters and Sets are intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and abscess), either by direct stick or Seldinger access technique.

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)

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510(k) Summary

Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter and Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, and Multipurpose Drainage Catheters and Sets

As required by 21 CFR, §807.92(c)

Date Prepared: April 25, 2018

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: Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter and Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, and Multipurpose Drainage Catheters and Sets
Common Name: Biliary, Nephrostomy, Multipurpose Percutaneous Drainage Catheters
Classification Name: • 21 CFR §876.5010, Biliary catheter and accessories, Class II, Product Code FGE
• 21 CFR§878.4200, Introduction/drainage catheter and accessories, Class I, Product Code GBO
• Pre-Amendment, Catheter, Nephrostomy, Unclassified, Product Code LJE
Product Code: FGE, LJE, GBO
Classification Panel: Gastroenterology/Urology

Predicate Devices:
Exodus Array Multipurpose Drainage Catheter, Exodus Nuance Nephrostomy Drainage Catheter, and Exodus Believe Biliary Drainage Catheter cleared on September 24, 2015 (K152069).

Device Description:
The Gordon Large-Bore Curved Drainage Catheter is a drainage catheter that aspirates abscess cavity contents. The catheters are manufactured from radiopaque polyether-urethane material with hydrophilic coating on the surface of the catheter and are designed with six sideports at the distal curve. The catheters are available in diameters ranging from 16 to 22 French and in a length of 40 cm. The device includes flexible and rigid catheter introduction stiffening cannulas that aid in the placement of the catheter.

The Nephrostomy Pigtail Drainage Catheter is a drainage catheter used to drain urine from the kidney. The catheter is manufactured from radiopaque polyurethane tubing with a distal pigtail tip. The catheter is manufactured with six drainage sideports spaced within the pigtail curve. The catheter is available in a diameter of 8.3 French and in a length of 30 cm. The catheter is supplied with a Peel-Away straightener. The Percutaneous Nephrostomy Set is composed of the 8.3 Fr Nephrostomy Pigtail Drainage Catheter and several set components, including dilators, a wire guide, a Trocar needle, a Chiba needle, a connecting tube with a stopcock, and a fixation device.

The Pigtail Drainage Catheter Needle Set includes a drainage catheter used in multiple drainage applications, including nephrostomy, abscess drainage, and other abdominal cavity drainage procedures. The catheters are manufactured from radiopaque polyurethane tubing with a pigtail distal curve configuration. Four, six, or eight sideports are spaced evenly within the pigtail curve. The catheters are available in diameters of 5.0, 6.0, 7.0 and 8.3 French and in lengths of 15 or 25 cm. The Pigtail Drainage Catheter Needle Set is supplied with a Peel-Away straightener and a rigid stiffening cannula composed of a stainless steel needle, trocar stylet, and loading obturator.

The Multipurpose Drainage Catheters are used in a variety of drainage applications, e.g., nephrostomy, biliary, and abscess. There are 13 types of multipurpose drainage catheters.
and/or sets that fall into three different groups depending on the type of loop-locking mechanism, i.e., catheters without a locking mechanism, catheters with a Mac-Loc locking mechanism, and catheters with a Cook-Cope locking mechanism. Six product lines (Amplatz Universal Drainage Catheter and Set, Straight or Straight- Drain™ Drainage Catheter, Multipurpose Drainage Catheter, Universal Curved Drainage Catheters, Ring Biliary Duct Drainage Catheter, and Soft-Shaft Malecot Drainage Catheters) are designed without a locking mechanism. Four product lines (Multipurpose Drainage Catheter and Set, Dawson-Mueller Drainage Catheter and Set, Multipurpose Small Pigtail Drainage Catheter, and Biliary Drainage Catheters) are designed with a Mac-Loc® Locking Mechanism. Three product lines (Multipurpose Drainage Catheter, Biliary Drainage Catheter, and Cope Proximal Biliary Loop Catheter) are designed with a Cook-Cope or Luer lock Cook-Cope locking mechanism. The catheters are available in diameters ranging from 5.0 to 20.0 French and in lengths ranging from 15 to 60 cm. All catheters are manufactured from radiopaque polyether-urethane material. Most of the catheters are designed with distal curve configurations. The catheters may have a hydrophilic coating applied to their surface. The catheter size, number of sideports, distal tip configuration, and loop-locking mechanism are specific to the product type and drainage set specification. Many of these devices are supplied with a flexible and/or rigid stiffening cannula, as well as a catheter fixation device. The Multipurpose Drainage Set is composed of the Multipurpose Drainage Catheter and several set components, including a wire guide, dilator(s), a Neff percutaneous introducer set, and a connecting tube with a stopcock.

**Indications for Use:**

- The Gordon Large-Bore Curved Drainage Catheter is intended for abscess drainage.
- The Nephrostomy Pigtail Drainage Catheter and the Percutaneous Nephrostomy Set are intended for external urine drainage from the renal pelvis.
- The Pigtail Drainage Catheter Needle Set is intended for percutaneous external drainage in multiple applications (e.g., nephrostomy, abscess drainage and other abdominal cavity drainage procedures).
- The Multipurpose Drainage Catheters and Sets are intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and abscess), either by direct stick or Seldinger access technique.
Comparison to Predicates:

The proposed devices are considered to be substantially equivalent to the predicate devices, the Exodus Array Multipurpose Drainage Catheter, Exodus Nuance Nephrostomy Drainage Catheter, and Exodus Believe Biliary Drainage Catheter (cleared under K152069), in that they have the same intended use, which is to provide percutaneous drainage of fluid. Additionally, the subject devices have similar technological characteristics, methods of placement, and principles of operation to the predicate devices. The differences between the subject device and the predicate device include indications for use, dimensions, materials, presence of hydrophilic coating, radiopaque marker and depth marker, locking mechanisms, distal tip configurations, set components, catheter indwell time, and sterilization.

The substantial equivalence comparison between the subject devices and the predicate devices is provided in Table 1.
## Table 1 Substantial Equivalence Comparison Table

<table>
<thead>
<tr>
<th>Device</th>
<th>Predicate Device</th>
<th>Subject Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Number</td>
<td>876.5010</td>
<td>878.4200</td>
</tr>
<tr>
<td>Regulation Description</td>
<td>Biliary catheter and accessories</td>
<td>Introduction/drainage catheter and accessories (GBO)</td>
</tr>
<tr>
<td>Product Code</td>
<td>FGE, LJE, GBO</td>
<td>GBO</td>
</tr>
<tr>
<td>Classification</td>
<td>Class II</td>
<td>Class I</td>
</tr>
</tbody>
</table>

### Indication For Use
- Exodus Array Multipurpose Drainage Catheters are intended for percutaneous drainage of fluid or air in the chest, abdomen and pelvis, e.g., abscesses, cysts, pneumothoraces, and other general purpose drainage applications.
- Exodus Nuance Nephrostomy Drainage Catheters are intended for percutaneous drainage of fluid collections in the urinary system.
- Exodus Believe Biliary Drainage Catheters are intended for percutaneous drainage of the biliary tree.

- The Gordon Large-Bore Curved Drainage Catheter is intended for abscess drainage.
- The Nephrostomy Pigtail Drainage Catheter is intended for external urine drainage from the renal pelvis.
- The Percutaneous Nephrostomy Set is intended for external urine drainage from the renal pelvis.
- The Pigtail Drainage Catheter Needle Set is intended for percutaneous external drainage in multiple applications (e.g., nephrostomy, abscess drainage and other abdominal cavity drainage procedures).
- Multipurpose Drainage Catheters are intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and abscess), either by direct stick or Seldinger access technique.
Cook Incorporated - Traditional 510(k)
Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter and Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, and Multipurpose Drainage Catheter and Set
25 April 2018

Table 1 Substantial Equivalence Comparison Table (continued)

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<tr>
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<tbody>
<tr>
<td></td>
<td>Gordon Large-Bore Curved Drainage Catheter</td>
<td>Nephrostomy Pigtail Drainage Catheter/ Percutaneous Nephrostomy Set</td>
</tr>
<tr>
<td></td>
<td>Exodus Array Multipurpose Drainage Catheter, Exodus Nuance Nephrostomy Drainage Catheter, Exodus Believe Biliary Drainage Catheter – K152069</td>
<td>Gordon Large-Bore Curved Drainage Catheter</td>
</tr>
<tr>
<td>Catheter Size (Fr)</td>
<td>6, 8, 10, 12, 14</td>
<td>16, 18, 20, 22</td>
</tr>
<tr>
<td>Catheter Length (cm)</td>
<td>15, 25, 35</td>
<td>40</td>
</tr>
<tr>
<td>End Hole Size (inch)</td>
<td>0.038</td>
<td>0.038</td>
</tr>
<tr>
<td>Catheter Material</td>
<td>Blended: Carbothane 55D (70%) Carbothane 95A (30%)</td>
<td>Polyether-urethane</td>
</tr>
<tr>
<td>Hydrophilic Coating</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Radiopaque Marker</td>
<td>Polymer Marker band on select Multipurpose Catheters and all Biliary Drainage Catheters</td>
<td>None</td>
</tr>
<tr>
<td>Shaft Depth Markers</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Locking Mechanism</td>
<td>SureTwist Hub</td>
<td>None</td>
</tr>
<tr>
<td>Distal Tip Config.</td>
<td>Locking Pigtail</td>
<td>J-shaped</td>
</tr>
<tr>
<td>Sideports</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Components</td>
<td>Plastic Stiffening Cannula, Metal Stiffening Cannula, Trocar</td>
<td>Flexible Stiffening Cannula, Rigid Stiffening Cannula, Trocar Stylet</td>
</tr>
</tbody>
</table>

¹ Includes Peel Away Smooth, Peel Away Smooth with Fan, and Peel Away Smooth with Flange.
Cook Incorporated - Traditional 510(k)
Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter and Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, and Multipurpose Drainage Catheter and Set
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<td>Gordon Large-Bore Curved Drainage Catheter, Nephrostomy Pigtail Drainage Catheter/ Percutaneous Nephrostomy Set, Pigtail Drainage Catheter Needle Set, Multipurpose Drainage Catheters and Sets</td>
</tr>
<tr>
<td>Indwell Time</td>
<td>3 months</td>
<td>3 months</td>
</tr>
<tr>
<td>Packaging</td>
<td>Tyvek/Mylar (PET/LDPE) Pouch</td>
<td>Inner/Outer Tyvek Peel Pouch</td>
</tr>
<tr>
<td>Sterilization method</td>
<td>Ethylene oxide</td>
<td>Identical</td>
</tr>
<tr>
<td>Sterility level</td>
<td>$10^{-6}$</td>
<td>$10^{-6}$</td>
</tr>
</tbody>
</table>

1. One of the 8.5 Fr Straight-Drain™ Drainage Catheters is designed with no sideports; however, the lack of sideports does not compromise the drainage of the liquid because all of the subject drainage catheters are open-ended. The Soft-Shaft Malecot Drainage Catheters are designed with Malecot slits instead of sideports.
2. The indwell time of the Exodus Array Multipurpose Drainage Catheter is 3 months according to its IFU; the indwell time of the Exodus Nuance Nephrostomy Drainage Catheter and Exodus Believe Biliary Drainage Catheter is unknown.
Technological Characteristics:

Performance and biocompatibility testing was conducted in accordance with applicable standards to confirm the reliable performance of device characteristics. The following tests have been conducted on the drainage catheters, subject of this submission, to ensure reliable design and performance under the specified design requirements:

- Catheter/Set Compatibility – Testing performed demonstrated the drainage catheters and sets met the compatibility requirements.
- Simulated Bile Soak – Test articles studied in tensile, gravity flow rate, and kink testing had undergone simulated bile soak prior to the tests.
- Tensile Testing – Testing performed on the components per applicable ISO and USP standards demonstrated that the devices met the acceptance criteria.
- Gravity Flow Rate Testing – Testing performed prior to kink and after kink testing per applicable standards demonstrated that the devices met the acceptance criteria.
- Kink Testing – Testing characterized the kink radius of the drainage catheters.
- Radiopacity Testing – Testing performed per applicable standards demonstrated that the radiopacity of the drainage catheters met the acceptance criteria.
- Lubricity Testing – Testing performed demonstrated that the lubricity of the drainage catheters met the acceptance criteria.
- MRI Compatibility – Testing established the conditions for safety of the drainage catheters in the MR environment according to applicable standards.
- Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Subacute Toxicity, Subchronic Toxicity, Genotoxicity, and 4- and 13-Weeks Implantation demonstrated that the devices are biocompatible.

For these tests, all pre-determined acceptance criteria were met.

Conclusion

The results of the testing provide reasonable assurance that the subject devices have been designed so that they conform to the requirements of their intended use. The available evidence demonstrates that the subject devices are substantially equivalent to the predicate device, the Exodus Array Multipurpose Drainage Catheter, Exodus Nuance Nephrostomy Drainage Catheter, and Exodus Believe Biliary Drainage Catheter, cleared on September 24, 2015 (K152069). The minor differences in the subject devices also do
not raise new questions of safety or effectiveness and therefore support a determination of substantial equivalence to the predicate device.