May 17, 2019

Cook Incorporated
Yan Li
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K183035
Trade/Device Name: Percutaneous Entry Set, Skinny Needle® with Chiba Tip, Disposable Two-part Trocar Needle
Regulatory Class: Unclassified
Product Code: LJE
Dated: April 10, 2019
Received: April 11, 2019

Dear Yan Li:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for
Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183035

Device Name

Percutaneous Entry Set

Indications for Use *(Describe)*

Used to establish a percutaneous tract into the renal pelvis for catheter placement or stone manipulation.

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.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*

K183035

Device Name

Skinny Needle® with Chiba Tip

Indications for Use *(Describe)*

Used under fluoroscopy or ultrasound for initial location and positioning within the renal collecting system during a percutaneous nephrostomy.

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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See PRA Statement below.

510(k) Number *(if known)*

K183035

Device Name
Disposable Two-part Trocar Needle

Indications for Use *(Describe)*

Used under fluoroscopy or ultrasound for initial location and positioning within the renal collecting system during a percutaneous nephrostomy.

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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2.0 510(k) Summary

Percutaneous Entry Set
Skinny Needle® with China Tip
Disposable Two-Part Trocar Needle
Traditional 510(k) Summary
21 CFR §807.92
Date Prepared: October 31, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Yan Li Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 335-3575 x104987
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Percutaneous Entry Set Skinny Needle® with Chiba Tip Disposable Two-part Trocar Needle
Common Name:	Catheter, Nephrostomy
Regulation:	Not available
Product Code:	LJE
Device Class:	Unclassified
Classification Panel:	Gastroenterology/Urology

Predicate Device:

- Percutaneous Nephrostomy Trocar System, American Edward Laboratories, K844090

Device Description:

- *Percutaneous Entry Set*

The Percutaneous Entry Set is comprised of a Skinny Needle® with Chiba Tip, a Disposable Two-Part Trocar Needle, 8 dilators and a wire guide.

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The Skinny Needle® is comprised of a stainless steel stylet inserted through a hubbed stainless steel cannula. The cannula has gauge size of 22 with a length of 20 centimeters. The distal end of the cannula is a Chiba tip, beveled at a 30° angle.

The Disposable Two-Part Trocar Needle is comprised of a stainless steel beveled stylet which can be inserted through a hubbed stainless steel cannula. The cannula comes in a gauge of 18 with lengths in 15 and 20 centimeters. When the beveled stylet is inserted through the cannula, the length from the distal endpoint of the cannula to the proximal starting point of the bevel on the wire is 0-2 millimeters. Needles have an optional Echotip® design, consisting of a series of very small dimples on the surface of the needle tip that enables it to be visible under ultrasound.

The dilators are manufactured from polyethylene tubing in 6.0, 7.0, 8.0, 9.0, 10.0, 12.0, 14.0 and 16.0 French sizes. All dilators measure 20 centimeters in length and have 8 to 15 millimeter taper with a 0.040 inch diameter thru hole.

The wire guide is characterized by a heavy-duty shaft, with a gradual transition to a very flexible distal tip. This wire guide type is manufactured in a 0.038 inch diameter, and measures 80 centimeters in length with a 3 millimeter Safe-T-J tip. This wire guide is constructed of a polytetrafluoroethylene coated stainless steel.

The Percutaneous Entry Set will be supplied sterile and is intended for one-time use. The set is packaged in a peel-open pouch with a 3-year shelf life.

- *Skinny Needle® with Chiba Tip*

The Skinny Needle® with Chiba Tip is also available for sale individually.

The Skinny Needle® with Chiba Tip will be supplied sterile and is intended for one-time use. The set is packaged in a peel-open pouch with a 3-year shelf life.

- *Disposable Two-Part Trocar Needle*

The Disposable Two-Part Trocar Needle is also available for sale individually.

The Disposable Two-Part Trocar Needle will be supplied sterile and is intended for one-time use. The set is packaged in a peel-open pouch with a 3-year shelf life.

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Indications for Use:

- *Percutaneous Entry Set*

Used to establish a percutaneous tract into the renal pelvis for catheter placement or stone manipulation.

- *Skinny Needle® with Chiba Tip*

Used under fluoroscopy or ultrasound for initial location and positioning within the renal collecting system during a percutaneous nephrostomy.

- *Disposable Two-part Trocar Needle*

Used under fluoroscopy or ultrasound for initial location and positioning within the renal collecting system during a percutaneous nephrostomy.

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include design specifications, dimensions, and materials. Characteristics of the subject devices that differ from the predicate device are supported by testing.

Performance Data:

Performance testing was performed in accordance with ASTM F 623-99 (2013) and FDA's Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters. The following testing was performed to demonstrate that the Percutaneous Entry Set, the Skinny Needle® with Chiba Tip and the Disposable Two-part Trocar Needle met applicable design requirements.

1. Biocompatibility
2. Sterilization
3. Packaging: Distribution and Stability
4. Shelf-life
5. Component Compatibility
6. Dilators
    a. Tensile Test

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b. Tip Integrity Test
c. Radiopacity Test

7. Needles
    a. Hub Union Strength Test
    b. Fluid Injection Test
    c. Echogenicity Test
    d. Corrosion Test

Conclusion:

The results of these tests provide reasonable assurance that the Percutaneous Entry Set, the Skinny Needle® with Chiba Tip and the Disposable Two-part Trocar Needle will perform as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate device. In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.