DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 24, 2017

Cook, Inc.
Mr. David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K171853
Trade/Device Name: Liver Access and Biopsy Sets
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 20, 2017
Received: June 21, 2017

Dear Mr. Lehr:

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" (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 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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K171853

Device Name
Liver Access and Biopsy Sets

Indications for Use *(Describe)*
The Liver Access and Biopsy Sets are intended for use in obtaining liver histology samples via jugular vein approach in adult and pediatric populations. The devices are intended to be used in the treatment of the following pediatric subgroups: infants, children, and adolescents.

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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**510(k) SUMMARY**

**As required by 21 CFR §807.92**
**Date Prepared: August 23, 2017**

## I. SUBMITTER

| | |
|---|---|
| Submission: | Traditional 510(k) Premarket Notification |
| Applicant: | Cook Incorporated |
| Contact: | David Lehr, RAC |
| Applicant Address: | Cook Incorporated<br>750 Daniels Way<br>Bloomington, IN 47404 |
| Contact Phone Number: | (812) 335-3575 ext. 102309 |
| Contact Fax Number: | (812) 332-0281 |

## II. DEVICE

| | |
|---|---|
| Trade Name: | Liver Access and Biopsy Sets |
| Common Name: | Catheter Introducer |
| Classification Name: | Introducer. catheter |
| Regulation/Class: | 21 CFR §870.1340/Class II |
| Product Code | DYB |

## III. PREDICATE DEVICE

Dextera TLAB® Patel Set® Transjugular Liver Biopsy System (K022634), manufactured by Argon Medical.

## IV. DEVICE DESCRIPTION

The Liver Access and Biopsy Sets described in this submission are sets of various components that facilitate transjugular access to the liver for the purpose of taking tissue samples for biopsy. Each set includes a Quick-Core Biopsy Needle of a length sufficient to reach the liver from the patient's jugular vein, as well as a combination of a stiffening cannula and an introducer sheath (fitted with a Check-Flo valve adapter) that provides support for the biopsy needle. Other components that are included in some of these sets are a straight catheter, a curved angiographic catheter, an introducer set, and/or a dilator. Each component is individually packaged in an inner Tyvek pouch. All inner pouches for a given set configuration are packaged within an outer Tyvek pouch.

The Quick-Core Biopsy Needle consists of a stainless steel cutting cannula with a beveled point stylet that is activated by a plunger in the device's handle. The distal end of the needle is constructed of an inner stylet and a specimen notch that captures the tissue sample when the needle is fired. The Quick-Core Biopsy Needle is available in two sizes (18 gage and 19 gage)

and in lengths of 48 and 60 cm. The combination of 14 gage stainless steel stiffening cannula and 7 Fr radiopaque sheath, available in lengths of 53.5 or 32.5 cm, provides access to the hepatic vein and support for the biopsy needle. Other available components include a 5 Fr straight Teflon catheter with a length of 39 or 62 cm; a 5 Fr curved angiographic catheter with a length of 80 cm made of radiopaque nylon and stainless steel braiding; a 9 Fr dilator made of polyethylene tubing with a length of 38 cm; and a Check-Flo Introducer Set consisting of an introducer made of radiopaque fluorinated polyethylene with a radiopaque band incorporated into its tip and a dilator made of polyethylene tubing.

## V. INDICATIONS FOR USE

The Liver Access and Biopsy Sets are intended for use in obtaining liver histology samples via jugular vein approach in adult and pediatric populations. The devices are intended to be used in the treatment of the following pediatric subgroups: infants, children, and adolescents.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cook's Liver Access and Biopsy Sets and the predicate device, the Dextera TLAB® Patel Set® Transjugular Liver Biopsy System (K022634) manufactured by Argon Medical, are substantially equivalent in that they have similar indications for use, technological characteristics, methods of construction, and principles of operation. The differences between the subject device and the predicate device, including identification of the target population, materials, and component dimensions, were appropriately assessed and do not present any new questions of safety and/or effectiveness. Based on the comparison of the design, indications for use, materials, fundamental technology, and principles of operation, the subject device is considered to be substantially equivalent to the currently marketed predicate device. The substantial equivalence comparison of the subject device to the predicate is provided in the following table.

Substantial Equivalence Comparison Table

| | **PREDICATE DEVICE** | **SUBJECT DEVICE** |
|---|---|---|
| | **Dextera TLAB Patel Set (K022634)** | **Liver Access and Biopsy Sets** |
| Manufacturer | Argon Medical | Cook Inc. |
| Regulation Number<br>Product Code<br>Classification Name<br>Class | 21 CFR §870.1340<br>DYB<br>Introducer, Catheter<br>II | Identical |

Substantial Equivalence Comparison Table (continued)

| | PREDICATE DEVICE | SUBJECT DEVICE |
|---|---|---|
| | **Dextera TLAB Patel Set (K022634)** | **Liver Access and Biopsy Sets** |
| Indications for Use | Intended to be used for percutaneous transjugular liver access during diagnostic and interventional procedures.*<br><br>For Transjugular Liver Biopsy* | The Liver Access and Biopsy Sets are intended for use in obtaining liver histology samples via a jugular vein approach in adult and pediatric populations. |
| **Core Components** | | |
| ***Biopsy Needle*** | | |
| Needle diameter (gage) | 18, 19 | Identical |
| Needle length (cm) | 60 | 48, 60 |
| Throw length (mm) | 20 | Identical |
| ***Transjugular Liver Access Assembly (stiffening cannula/introducer sheath combination)*** | | |
| Sheath outer diameter (Fr) | 7 | Identical |
| Sheath length (cm) | 51 | 32.5, 53.5 |
| Cannula material | Stainless steel | Identical |
| Cannula diameter (ga) | Unknown | 14 |
| Cannula length (cm) | 51 | 32.5, 53.5 |
| **Additional Set Components** | | |
| ***Straight Catheter*** | | |
| Catheter material | Unknown | Teflon |
| Catheter outer diameter (Fr) | 5 | Identical |
| Endhole size (in) | Unknown | 0.035 |
| Catheter length (cm) | 65 | 39, 62 |
| ***Curved Catheter*** | | |
| Catheter outer diameter (Fr) | 5 | Identical |
| Catheter length (cm) | 76 | 80 |
| ***Dilator*** | | |
| Outer diameter (Fr) | Not applicable | 9 |
| Endhole size (in) | | 0.038 |
| Length (cm) | | 20 |
| ***Check-Flo Introducer Set*** | | |
| Sheath outer diameter (Fr) | Not applicable | 9 |
| Endhole diameter (in) | | 0.035 |
| Sheath length (cm) | | 20 |
| Dilator length (cm) | | 27 |
| ***Tissue Removal Swabs*** | | |
| Quantity | 4 | Not applicable |
| Length (cm) | 10 | |
| Materials | Polyurethane foam tip, nylon handle | |

Substantial Equivalence Comparison Table (continued)

| | PREDICATE DEVICE | SUBJECT DEVICE |
|---|---|---|
| | **Dextera TLAB Patel Set (K022634)** | **Liver Access and Biopsy Sets** |
| ***Packaging and Sterilization*** | | |
| Shelf Life | Unknown | 3 years |
| Sterilization method | Gamma irradiation | EtO |
| Sterilization | SAL $10^{-6}$ | Identical |
| Packaging | Tyvek™/PET/PE pouch | Identical |

*****This device was cleared as the Co-Axial Introducer Needle by FDA on Nov. 6, 2002, and was submitted by Promex Inc., which was later acquired by Argon Medical Devices. The access components were meant to be used with a biopsy needle cleared separately, and the device's IFU currently states that it is intended "for transjugular liver biopsy."

## VII. PERFORMANCE DATA

The subject devices underwent the applicable testing listed below to ensure reliable design and performance under the testing parameters. Performance and biocompatibility testing was conducted in accordance with applicable FDA guidance documents or ISO Standards to confirm the reliable performance of critical device characteristics. Testing on the Torcon NB® Advantage Catheter is not included, because this device has been previously cleared by FDA under 510(k) number K161822.

Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Hemocompatibility (Hemolysis, Complement Activation, Partial Thromboplastin Time), and Material-mediated Pyrogenicity tests were performed on all components of the subject device or on representative devices. All test results met the acceptance criteria, where applicable, or demonstrated that the device is biocompatible.

Performance Testing – The components in the subject device were subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests for the core components (i.e., the Quick-Core Biopsy Needle and Transjugular Liver Access assembly) and the accessories are listed below. In addition to the tests listed below, dimensional, surface and compatibility analysis was performed on all components in the subject device to verify that the critical dimensions met the predefined acceptance criteria, that the surfaces of the devices were free from defects, and that the set components were compatible.

Testing performed on the core components includes the following:

- Radiopacity – Testing performed demonstrated that the devices were visible in the radiographic image and were qualitatively assessed to be non-inferior to the user-defined

standard, following the method described in ASTM F640-12, "Standard Test Methods For Determining Radiopacity for Medical Use."

- Corrosion Resistance – Testing performed demonstrated that there is no effect on the functional performance of the components.
- Tensile – Testing performed on the components per applicable ISO and JIS standards demonstrated that the devices met the acceptance criteria.
- Torque – Testing performed demonstrated that the peak torque was within the clinical requirement.
- Resistance to Breakage – Testing performed per the test method described in Annex C of BS EN ISO 9626 demonstrated that the test articles met the acceptance criteria.
- Force to Fire, Force to Prime, and Cyclic Fatigue – Testing performed on the Quick-Core Biopsy Needle determined the force necessary to prime and fire the needle and the cyclic fatigue of the needles when they are repeatedly fired.
- Liquid Leakage – Testing performed on catheter per the test method described in relevant annexes of ISO 10555-1:2013 met the acceptance criteria.

<u>Testing performed on the additional set components includes the following:</u>

- Teflon Catheter Hub-to-Shaft and Shaft Tensile – Testing in accordance with BS EN ISO 11070:2014 showed that the Teflon catheter withstood a minimum tensile force. The acceptance criteria for this study were met.
- Teflon Catheter Liquid Leakage – Testing in accordance with BS EN ISO 10555-1:2013 showed that the Teflon catheter did not leak liquid.
- Teflon Catheter Air Leakage – Testing in accordance with BS EN ISO 10555-1:2013 – Annex D showed that the Teflon catheter did not leak air.
- Dilator Hub-to-Shaft Tensile – Testing in accordance with BS EN ISO 11070 showed the peak load of the hub-to-shaft were greater than or equal to 15 N.
- Performer Introducer Tensile – Testing performed in accordance with Annex C of BS EN ISO 11070 demonstrated that the various joints of the introducer met the peak tensile force requirements of the acceptance criteria.
- Performer Introducer Liquid Leakage – Testing performed in accordance with clinical observations verified that the Check-Flo body-to-shaft connection of the test articles met the liquid leakage requirements.
- Performer Introducer Hemostasis Valve Liquid Leakage – Testing in accordance with ISO 11070 Annex E demonstrated that the test articles did not leak liquid past the hemostasis valve. The acceptance criteria were met.

## VIII. CLINCIAL EVIDENCE

A systematic literature search was conducted to support the use of the subject device in adult and pediatric patients. Literature databases including Google Scholar, Embase, and PubMed were used for this search. The literature search identified 43 published journal articles that support the use of the subject device in a population ranging from 1 month to 94 years. A list of citations to the articles used for a substantial equivalence determination is presented below.

Specifically, the data reports use of the Liver Access and Biopsy Set with a 48 or 60 cm long 18 or 19 ga needle and indicates a success rate of approximately 95%, with a diagnosis rate ranging from 68% to 100%. The types and rates of complications are consistent with those reported by Kalambokis et al. With regard to use in a pediatric population, data from a study published by Hoffer demonstrates the successful use of the subject device (Liver Access and Biopsy Set with 19 ga biopsy needle) in a population with an age range of 7 months to 22 years. The study compared the use of percutaneous biopsy to the transjugular liver biopsy in 44 pediatric oncology patients. Patients at an increased risk of bleeding underwent the transjugular approach, and the percutaneous approach was used for patients without an increased risk of bleeding. The success rate of obtaining a biopsy using the transjugular route was 100%, and all biopsies yielded samples that were sufficient for diagnostic studies. There were no bleeding or major complications observed with the use of transjugular liver biopsy, whereas bleeding occurred in 14% of the cases using percutaneous biopsy. Minor complications such as transient arrhythmia, carotid artery puncture, and contrast extravasation (peritoneal and biliary) resolved without any clinical sequelae and occurred at a rate that is comparable to the incidence rates reported by Kalambokis et.al. Data from other studies focused on the pediatric population are consistent with the results published by Hoffer and reports successful use of the subject device (Liver Access and Biopsy Set with 18 ga and 19 ga biopsy needle) in patient ages ranging from 10 months to 19 years.

Finally, the study by Behrens et al. compared the adequacy of liver biopsy samples obtained using the subject device (with an 18 ga Quick-Core biopsy needle) and the predicate device (with an 18 ga Flexcore needle) in 233 patients. The subject device was used in 141 patients (age range 12 to 87 years), whereas the predicate device was used in 92 patients (age range 11 to 86 years), and the overall success rate was 99.6% with an overall diagnosis rate of 96%.

Seven major complications were reported for the Quick-Core procedures, and six major complications were reported for the Flexcore procedures. There was no significant difference in the rate of major complications between groups. Major complications included hemoperitoneum,

subcapsular hematoma, and death. The deaths were associated with underlying disease and severe liver failure and were not attributed to the procedure. Abdominal pain (the only minor complication) was reported by patients in both groups, and there was no significant difference in the rate of this event between groups.

Overall, the literature summary supports the indications for use of the subject device (i.e., for use in obtaining liver histology samples via a jugular vein approach in adult and pediatric populations) and does not raise any new questions of safety and effectiveness.

1. Hoffer FA. Liver biopsy methods for pediatric oncology patients. *Pediatr Radiol.* Jul 2000;30(7):481-488.
2. Behrens G, Ferral H, Giusto D, Patel J, Van Thiel DH. Transjugular liver biopsy: comparison of sample adequacy with the use of two automated needle systems. *J Vasc Interv Radiol.* Mar 2011;22(3):341-345.
3. Kalambokis G, Manousou P, Vibhakorn S, Marelli L, Cholongitas E, Senzolo M et al. Transjugular liver biopsy—indications, adequacy, quality of specimens, and complications—a systematic review. J Hepatol 2007;47:284-94.

## IX. CONCLUSIONS

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 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, the Dextera TLAB® Patel Set® Transjugular Liver Biopsy System.