March 9, 2018

Cook Incorporated
Mr. David Lehr, RAC
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K171820
Trade/Device Name: Transjugular Liver Access Sets
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 15, 2018
Received: February 16, 2018

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.

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171820

Device Name
Transjugular Liver Access Sets

Indications for Use *(Describe)*
The Rosch-Uchida Transjugular Liver Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

The Ring Transjugular Intrahepatic Access Set is intended for transjugular liver access in diagnostic and interventional 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.

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

"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."

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

510(k) SUMMARY

As required by 21 CFR §807.92
Date Prepared: February 14, 2018

I. SUBMITTER

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

II. DEVICE

Trade Name:	Transjugular Liver Access Sets
Common Name:	Catheter Introducer
Classification Name:	Introducer, catheter
Regulation/Class:	21 CFR §870.1340/Class II
Product Code	DYB

III. PREDICATE DEVICE

GORE TIPS Set (K152913), manufactured by Creganna Medical.

IV. DEVICE DESCRIPTION

The Transjugular Liver Access Sets are comprised of various components that facilitate transjugular access to the liver for the purpose of performing diagnostic and interventional procedures. The sets are grouped into two basic types: the Ring Transjugular Intrahepatic Access Set and the Rösch-Uchida Transjugular Liver Access Set. Each set includes a core component comprised of a combination of either a stiffening cannula/Teflon catheter or needle stylet/Teflon catheter that facilitates access into the hepatic vasculature and the creation of a pathway into the portal vein. Other components included in some of these sets are a Check-Flo Introducer Set, selective catheters, and wire guides. The following components of the subject device sets have received prior 510(k) clearance: the Flexor Check-Flo Introducer Set (K142829), the van Andel Catheter (K170616), and the Torcon NB Advantage Catheter (K161822). 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 Ring Transjugular Intrahepatic Access Set's core component is a Colapinto Needle and Catheter Assembly. The Colapinto Needle is a hollow 16 gage stainless steel stiffening cannula

with a needle bevel and a length of 50.5 cm. It is matched with either a 9 Fr or 10 Fr Teflon catheter. The Rösch-Uchida Transjugular Liver Access Set's core component is a Stylet and Catheter Assembly that functions coaxially with a stiffening access cannula which provides access and support for the needle stylet/catheter assembly. The stylet is a 0.038 inch diameter stainless steel trocar with a length of 62.5 cm. It is matched with a 5.2 Fr Teflon catheter**.** The stiffening access cannula is a hollow 14 gage stainless steel tube with a length of 54.5 cm that is matched with 10 Fr Teflon catheter.

V. INDICATIONS FOR USE

The Ring Transjugular Intrahepatic Access Set is intended for transjugular liver access in diagnostic and interventional procedures.
The Rösch-Uchida Transjugular Liver Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Cook's Transjugular Liver Access Sets and the predicate device, the GORE TIPS Set (K152913) manufactured by Creganna 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 devices and the predicate device, including 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 devices are considered to be substantially equivalent to the currently marketed predicate device. The substantial equivalence comparison of the subject devices to the predicate is provided in the following table.

Substantial Equivalence Comparison Table

	PREDICATE DEVICE	**SUBJECT DEVICES**
	GORE TIPS Set (K152913)	**Transjugular Liver Access Sets**
Manufacturer	Creganna Medical	Cook Inc.
Regulation Number Product Code Classification Name Class	21 CFR §870.1340 DYB Introducer, Catheter II	Identical

Substantial Equivalence Comparison Table (continued)

	PREDICATE DEVICE	SUBJECT DEVICE
	GORE TIPS Set (K152913)	**Transjugular Liver Access Sets**
Indications for Use	The GORE TIPS Set, GORE TIPS Sheath, and GORE TIPS Needle are intended to be used together for percutaneous transjugular liver access during diagnostic and interventional procedures in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.	Intended for transjugular liver access in diagnostic and interventional procedures.
Set components that puncture through the hepatic vein, liver parenchyma, and portal vein	16 gage Stainless Steel Needle - 56 cm in length 10 Fr MDPE catheter - 49 cm in length	16 gage Stainless Steel Needle - 50.5 cm in length 9 or 10 Fr Teflon Catheter - 45.5 cm in length OR 0.038 inch Stainless Steel Needle Stylet - 62.5 cm in length 5.2 Fr Teflon Catheter - 62 cm in length 14 gage Stainless Steel Stiffening Access Cannula - 54.5 cm in length 10 Fr Teflon Catheter - 51.8 cm in length
Introducer Set		
Sheath Materials	PTFE liner, stainless steel coil Pebax 6333 Jacket	PTFE liner, stainless steel coil Nylon jacket
Sheath Marker Band	Platinum/Iridium	Identical
Sheath Hub Material	Grilamid	Nylon
Sheath Outer Diameter (Fr)	10	9, 10
Sheath Length (cm)	40	38.5, 40
Dilator Material	HDPE	Polyethylene
Dilator Hub Material	HDPE	Polyethylene
Dilator Length (cm)	47	40, 51
Dilator Endhole Size (in)	0.035	0.035, 0.038
Catheters		
Outer Diameter (Fr)	Not applicable	5
Length (cm)		80
Endhole Size (in)		0.035
Shaft Materials		Teflon (Van Andel) Nylon (Torcon NB)

Substantial Equivalence Comparison Table (continued)

	PREDICATE DEVICE	SUBJECT DEVICE
	GORE TIPS Set (K152913)	**Transjugular Liver Access Sets**
Wire Guides		
Wire Guide Diameter (in)	Not applicable	0.035
Wire Guide Lengths (cm)		180, 190
Wire Guide Materials		Stainless Steel PTFE Coating
Dilator		
Dilator Outer Diameter (Fr)	Not applicable	11, 12
Dilator Length (cm)		20
Dilator Endhole Size (in)		0.038
Dilator Shaft		Polyethylene
Dilator Hub		HDPE
Packaging/Sterilization/Shelf Life		
Packaging	Tyvek/Polyethylene-polyester Film	Identical
Sterilization (SAL 10^{-6})	EtO	Identical
Shelf Life	1 year	3 years

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 to confirm the reliable performance of critical device characteristics. Testing on specific introducer and catheter components (the Van Andel Catheter, the Torcon NB® Advantage Catheter, and the Flexor Check-Flo Introducer Set) is not included because these devices have been previously cleared by the FDA under 510(k) numbers K170616, K161822, and K142829, respectively.

Biocompatibility Testing - – Per ISO 10993-1 and FDA guidance, testing for Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Hemocompatibility(Hemolysis, Complement Activation, In Vivo Thrombogenicity), 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., set components that puncture through the hepatic vein, liver parenchyma, and portal vein) 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.
- Liquid Leakage, Air Leakage and Burst Pressure – Testing performed on catheter per the test method described in relevant annexes of ISO 10555-1:2013 met the acceptance criteria.
- 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.

Testing performed on the additional set components includes the following:

- 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 15N.
- Wire Guide Tensile Testing – Testing in accordance with ISO 11070:2014, Annex H showed that the pre-determined acceptance criteria were met.
- Wire Guide Corrosion Testing – Testing in accordance with Annex B of ISO 11070:2014 demonstrated that the pre-determined acceptance criteria were met.
- Wire Guide Flexing Test – Testing in accordance with the Annex G of ISO 11070:2014 demonstrated that the pre-determined acceptance criteria were met.
- Wire Guide Fracture Testing – Testing in accordance with Annex F of ISO 11070:2014 demonstrated that the pre-determined acceptance criteria were met.
- Wire Guide Torque Strength Testing – Characterization testing performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).
- Wire Guide Tip Flexibility – Characterization testing performed in accordance with the FDA Coronary and Cerebrovascular Guidewire Guidance (1995).

VIII. CONCLUSIONS

The results of testing provide reasonable assurance that the Transjugular Liver Access Sets 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 GORE TIPS Set (K152913), and do not raise new questions of safety or effectiveness. This supports a determination of substantial equivalence.