DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 21, 2016

Creganna Medical
Ms. Orla Connaughton
Director of Regulatory Affairs
Parkmore West
Galway, Ireland

Re: K152913
Trade/Device Name: GORE TIPS Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 14, 2016
Received: June 17, 2016

Dear Ms. Connaughton:

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" (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 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,

Brian D. Pullin -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152913

Device Name
GORE TIPS Set

Indications for Use *(Describe)*

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.

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

General Information

Date:	21 July 2016
Classification:	Class II, 21 CFR 870.1340, Catheter Introducer
Trade Name:	GORE® TIPS SET
Common Name:	Catheter Introducer
Model Numbers:	142097-01, 142098-01, 142099-01
Submitter:	Creganna Medical, Parkmore West, Galway, Ireland
Regulatory Contact:	Orla Hickey Regulatory Affairs Specialist Creganna Medical Parkmore West Galway, Ireland Tel: + 91 783438 Email: Regulatory@creganna.com Email: Orla.Hickey@creganna.com

Intended 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.

Predicate Device

- Cook® Medical Flexor® Check-Flo II® Introducer Set, K142829 (component of the Haskal Transjugular Intrahepatic Portal Access Set)
- Cook® Medical Needle Catheter Combination

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Device Description

The **GORE® TIPS Set** consists of the GORE® TIPS Sheath and the GORE® TIPS Needle, which may be supplied together or individually.

GORE® TIPS Sheath: Transjugular Liver Access Introducer Sheath and Dilator:

The GORE® TIPS Sheath consists of a flexible introducer sheath with a hemostatic valve and a dilator. The introducer sheath includes an inner PTFE layer, a stainless steel coil and an outer jacket. The dilator has a tapered leading end and provides dilatation of the access vessel. The dilator hub has a direction indicator to allow identification of the leading end curvature direction. The dilator hub may be locked into place in the hub of the introducer sheath to prevent the dilator backing out of the sheath.

GORE® TIPS Needle: Transjugular Liver Access Needle and Guiding Catheter:

The GORE® TIPS Needle consists of a stainless steel hollow shaft and a guiding catheter. The needle handle has a direction indicator to allow identification of the leading end curvature direction. The guiding catheter has a tapered leading end and provides protection around the sharp needle tip during vascular access. A white needle status band printed on the trailing end of the needle shaft ensures correct positioning of the guiding catheter around the needle shaft when covering the sharp needle tip. The guiding catheter hub has a direction indicator that identifies the leading end curvature direction.

The set is supplied as a single use sterile device.

Materials

The Creganna Medical GORE® TIPS Set is comprised of materials that are commonly used in medical device applications, including implantable medical devices. The biological safety tests performed in accordance with ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing) for external communicating devices, circulating blood, limited duration demonstrate that the device is biocompatible for its intended use.

The tests performed to demonstrate the biocompatibility of the device were:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity/Irritation

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- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
- Complement Activation Assay
- Thromboresistance

Summary of the Technological Characteristics of GORE TIPS Set compared to the Predicate Device

The GORE® TIPS Set and the equivalent commercialized predicate devices Cook® Medical Flexor® Check Flo® Introducer Set and Cook® Medical Needle Catheter Combination were evaluated for substantial equivalence in accordance with 510(k) "Substantial Equivalence" Decision-Making Process, as outlined in ODE Guidance Document No. K86-3, "Guidance on the CDRH Premarket Notification Review Program". The critical predictors of device safety and performance are compared utilizing clinical, technical and biological criteria.

In summary, no significant difference in clinical, technical and biological parameters was identified between the GORE® TIPS Set and the Cook® Medical Flexor® Check Flo® Introducer Set and Cook® Medical Needle Catheter Combination.

In fact, the clinical use of these devices is the same; they are used in the same locations within the body and have similar clinical performance criteria.

These devices have similar designs and principles of operations and the materials that are used meet the same biological standards. Based on this and the design and engineering data provided, the GORE® TIPS Set has been shown to be substantially equivalent to the commercialized Cook® Medical Flexor® Check Flo® Introducer Set and Cook® Medical Needle Catheter Combination devices.

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	GORE® TIPS Set **GORE® TIPS Sheath** **GORE® TIPS Needle**	**Cook® Medical Flexor® Check-Flo II® Introducer Set** **(component of the Haskal Transjugular Intrahepatic Portal Access Set)**	**Cook® Medical Needle Catheter Combination**
Manufacturer	Creganna Medical	Cook® Medical	Cook® Medical
CE Mark	In progress	Yes	Yes
FDA Clearance/Approval	N/A	Yes K142829 The Flexor® Check-Flo II® Introducer Haskal Transjugular Intrapetic Portal Access Set (possible pre-amendment device)	Yes (possible pre-amendment device)
Clinical Comparison			
Principle of Operation	To achieve the intended use of the GORE® TIPS Set, first access to the jugular vein using standard access techniques The Introducer sheath and dilator are inserted over the guidewire, advanced, and positioned in the hepatic vein and the dilator is removed. The needle and guide catheter is inserted into the introducer sheath and the Needle is used to puncture the hepatic vein, liver parenchyma and the portal vein.	To achieve the intended use of the Flexor Check-Flo II Introducer, access to the target vein should be gained using standard access techniques. The Introducer sheath and dilator are inserted over the guidewire, advanced, and positioned as required, the dilator is removed.	The needle and guide catheter are inserted into the introducer sheath and the Needle is used to puncture the hepatic vein, liver parenchyma and the portal vein.
Intended 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	Introducers are intended for the introduction of balloons, closed and non-tapered end	Needles are used to puncture where a native opening is not present.

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	GORE® TIPS Set **GORE® TIPS Sheath** **GORE® TIPS Needle**	**Cook® Medical Flexor® Check-Flo II® Introducer Set** **(component of the Haskal Transjugular Intrahepatic Portal Access Set)**	**Cook® Medical Needle Catheter Combination**
	procedures in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.	catheters or other diagnostic an interventional devices. The Haskal Transjugular Intrahepatic Portal Access Set is intended for transjugular liver access in diagnostic and interventional procedures.	In this case, the Needle is used to puncture the hepatic vein, liver parenchyma and the portal vein.
Contraindications	There are no known contraindications for these devices.	None known.	Unknown.
Single Use	Yes	Yes	Yes
Supplied Sterile	Yes	Yes	Yes
Technical and Biological Comparison			
Device Description	The GORE® TIPS Set consists of the GORE® TIPS Sheath and the GORE® TIPS Needle, which may be supplied together or individually. The GORE® TIPS Sheath consists of an introducer sheath with a hemostatic valve and a dilator. The GORE® TIPS Needle consists of a stainless steel hollow shaft with a Needle tip and a guiding catheter.	The Flexor® Check-Flo II® Introducer consists of an introducer sheath with a hemostatic valve and a dilator.	The Needle Catheter Combination consists of a stainless steel hollow shaft with a Needle tip and a guiding catheter.

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	GORE® TIPS Set **GORE® TIPS Sheath** **GORE® TIPS Needle**	**Cook® Medical Flexor® Check-Flo II® Introducer Set** **(component of the Haskal Transjugular Intrahepatic Portal Access Set)**	**Cook® Medical Needle Catheter Combination**
Introducer Sheath Compatibility	10Fr	10Fr	N/A
Introducer Sheath Working Length (cm)	Introducer Sheath: 40cm Dilator: 47cm	Introducer Sheath: 38.5cm Dilator – not referenced	N/A
Introducer Sheath Curve angle	35°	N/A	N/A
Sheath composition	PTFE Liner SS Coil Pt/IR markerband Pebax 6333 Jacket Grilamid hub Hemostasis seal	Liner Coil Radiopaque markerband Nylon Jacket Polymer hub Hemostasis seal	N/A
Dilator ID / Guidewire Compatibility	≤ 0.035”	≤ 0.035”	N/A
Dilator material	HDPE Extrusion	Polymer Extrusion	N/A

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	HDPE Hub	Polymer Hub	
Needle Gauge	16Ga	N/A	16Ga
Needle Working Length (cm)	Needle: 56cm Needle Guide: 49cm	N/A	Needle: 50.5cm Needle Guide 45.5cm
Needle Curve angle	35°	N/A	N/A
Needle Material	304 Stainless Steel Grilamid Hub	N/A	Stainless Steel Hypotube Stainless steel hub
Needle Guide ID / Guidewire Compatibility	≤ 0.035”	N/A	N/A
Needle Guide Material	MDPE Extrusion HDPE Hub	N/A	Polymer Extrusion SS Hub
ISO 10555-1	Needle, Needle guide and Dilator meet requirements	Meets requirements	Meets requirements
ISO 11070	Introducer Sheath meets requirements	Meets requirements	N/A

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ISO 9626	Needle Meets requirements	N/A	Meets requirements
Biocompatibility **ISO 10993-1**	Meets ISO requirements for externally communicating, circulating blood, limited contact (<24 hours)	Meets Requirements	Meets Requirements
Shelf-Life	1 years	3 years	3 years
Packaging / Shipping **ISO 11607-1, ISO 11607-2, ASTM D4169**	Meets Requirements	Meets Requirements	Meets Requirements
Clinical, Technological, Biological Equivalence	Yes	Yes	Yes
Justification for Equivalence	-	Designed and manufactured using the same or similar standards.	Designed and manufactured using the same or similar standards.
	-	Manufactured using the same or similar materials used in the same anatomical location	Manufactured using the same or similar materials used in the same anatomical location
	-	Technological characteristics such as size are similar.	Technological characteristics such as size are similar.

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	GORE® TIPS Set **GORE® TIPS Sheath** **GORE® TIPS Needle**	**Cook® Medical Flexor® Check-Flo II® Introducer Set** **(component of the Haskal Transjugular Intrahepatic Portal Access Set)**	**Cook® Medical Needle Catheter Combination**
	-	Similar biological characteristics.	Similar biological characteristics.
	-	Similar clinical performance, patient populations, intended use and principle of operation.	Similar clinical performance, patient populations, intended use and principle of operation.

Table 5-1 Substantial Equivalence Comparison Table of Proposed Device and Predicate Device

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Non Clinical Information

The determination of substantial equivalence is also based on an assessment of non-clinical engineering tests, as listed in **Table 5-2** and **Table 5-3**.

Design Verification Tests	
Sheath and Dilator	**Needle and Needle Guide**
Sheath Length	Needle Length
Sheath Size Diameter	Needle Size Diameter(s)
Introducer Sheath Curvature	Needle Curvature
Dilator Working Length	Needle Tip Geometry
Dilator ID	Needle Guide Length
Dilator Shaft OD and Tip Geometry	Needle Guide Outer Diameter (OD)
Dilator Curvature	Needle Guide Inner Diameter (ID)
Flushing port tubing and 3 Way Stopcock	Needle Guide Curvature
Sheath Hub Seal	Needle Hub Directional Indicator
Dilator Directional Indicator	Needle Guide Hub Directional Indicator
Introducer Sheath Directional Indicator	Needle Puncture Force
Sheath Kink Resistance	Needle Puncture Force
Valve Hemostasis	Bond Strengths of Assembled Components, Needle Hub and Needle Guide Hub
System Leak (Pressure Integrity)	System Leak (Pressure Integrity)
Bonds Strength of Assembled Components, Dilator Hub Sheath Hubs and Introducer Sheath Shaft.	Needle Shaft Marker
Sheath/Dilator Interface	Needle and Needle Guide Directional Indicator
Visual Appearance	Visual Appearance

Table 5-2: List of Design Verification Tests

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Design Validation Tests	
Sheath and Dilator	**Needle and Needle Guide**
Distinguishable feature between the Dilator and Needle Guide Components	Needle Guide Curvature
Sheath Deliverability (Push, Track, and Withdrawal)	Needle and Needle Guide Deliverability (Push, Track, and Withdrawal)
Dilator Shaft and Tip Deliverability (Push, Track, and Withdrawal)	Needle Kink Resistance (Fatigue Resistance)
Radiopacity	Needle Pushability / Column Strength
Flush Port Tubing and 3 Way Stopcock	Needle Shaft Markers
Sheath/Dilator Interface.	Needle and Needle Guide Radiopacity
VIATORR® Device Compatibility	Needle Echogenic Performance
Compatibility with Ancillary Devices and Fluids.	Needle / Needle Guide Interface
Transjugular Liver Access Set (TLAS) Needle Compatibility.	Guidewire Compatibility
VIATORR® Access Sleeve – Black Mark Alignment	Introducer compatibility
VIATORR® Loading Tool – Bottoms out distal to the flush port	Needle Guide Hub Interface
Ergonomic Sheath Hub	Needle Hub Interface
Ergonomic Dilator Hub	Needle and Needle Guide Hub Ergonomics
Stackable and Storable in Use Environment	Stackable and Storable in Use Environment
Labeling Information	Labeling Information

Table 5-3: List of Design Validation Tests

The test results demonstrate that the GORE® TIPS Set meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate device.

Clinical Information

Clinical studies were not deemed necessary for the Gore® TIPS Set since bench testing and a clinical literature review were sufficient to demonstrate substantial equivalence by way of comparison to a legally marketed predicate device.

Summary of Substantial Equivalence

Creganna Medical believes the GORE® TIPS Set is substantially equivalent to the predicate device based on the nonclinical and clinical literature review as discussed above. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products, and demonstrate that the device is substantial equivalent and performs as well as the predicate device.