November 20, 2019

Cook Ireland Ltd.
Jane Kennedy
Senior Regulatory Affairs Specialist
O'Halloran Road, National Technology Park
Limerick, V94 N8X2
IRELAND

Re: DEN180062
Trade/Device Name: EchoTip® Insight™ Portosystemic Pressure Gradient Measuring System
Regulation Number: 21 CFR 876.1050
Regulation Name: Endoscopic transhepatic venous access needle
Regulatory Class: Class II
Product Code: QIJ
Dated: November 16, 2018
Received: November 19, 2018

Dear Jane Kennedy:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System is indicated to directly measure pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System, and substantially equivalent devices of this generic type, into Class II under the generic name endoscopic transhepatic venous access needle.

FDA identifies this generic type of device as:

> **Endoscopic transhepatic venous access needle.** An endoscopic transhepatic venous access needle is inserted through the liver into the patient's portal/hepatic venous system under endoscopic ultrasound guidance. It is connected to a separate device intended to measure a physiological parameter.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 19, 2018, FDA received your De Novo requesting classification of the EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System. The request was submitted under section 513(f)(2) of the FD&C Act. To classify the EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System, can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility testing Pyrogenicity testing
Infection	Sterilization validation Pyrogenicity testing Shelf life testing Package integrity testing
Use error leading to: • Access site hemorrhage/thrombosis • Portal vein penetration leading to intrahepatic bleeding	Labeling
Improper patient management due to inaccurate measurement	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the endoscopic transhepatic venous access needle is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Performance data must demonstrate the sterility of the patient-contacting components of the device.

3. The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

4. Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility and package integrity over the labeled shelf life.

5. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be tested:
    a. Needle crumple testing;
    b. Tensile testing;
    c. Dimensional verification for all components; and
    d. Simulated use testing.

6. Labeling must include the following:
    a. Instructions for use, including specific instructions regarding device preparation;
    b. The recommended training for safe use of the device; and
    c. A shelf life for any sterile components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the endoscopic transhepatic venous access needle they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Thelma Valdes at (301) 796-9621.

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health