



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

July 31, 2017

Cook Ireland Ltd.  
Orla Gunning  
Regulatory Affairs Specialist  
O'Halloran Road, National Technology Park,  
Limerick  
Ireland

Re: K171623  
Trade/Device Name: Nasal Pancreatic Drainage Set  
Regulation Number: 21 CFR§ 876.5010  
Regulation Name: Biliary Catheter and Accessories  
Regulatory Class: II  
Product Code: FGE  
Dated: May 31, 2017  
Received: June 2, 2017

Dear Orla Gunning:

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,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K171623

Device Name

Nasal Pancreatic Drainage Set

Indications for Use (Describe)

This device is used for temporary endoscopic drainage of the pancreatic duct through the nasal passage by use of an indwelling catheter.

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.\***

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## **Section 5: 510(k) Summary**

### **I. SUBMITTER**

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Date Prepared: July 31, 2017

### **II. DEVICE**

Trade Name of Device: Nasal Pancreatic Drainage Set

The model numbers are NPDS-5 and NPDS-7.

Common or Usual Name: Drainage Catheter

Classification Name: Biliary, Catheter and Accessories (21 CFR 876.5010)

Regulatory Class: II

Product Code: FGE

### **III. PREDICATE DEVICE**

Predicate: Cook Zimmon Endoscopic Pancreatic Stent cleared under 510(k):  
K900923 cleared on October 26, 1990

Reference Device Number One: Cook Nasal Biliary Drainage Set cleared under 510(k)  
K896323 cleared on April 09, 1990

Reference Device Number Two: Boston Scientific Corporation, Advanix™ Pancreatic Stent and Naviflex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers cleared under 510(k) K133700 on May 14, 2014

### **IV. DEVICE DESCRIPTION**

The Nasal Pancreatic Drainage Set consists of a drainage catheter, nasal transfer tube and drainage connecting tube. The drainage catheter has flaps, side ports and a touhy-borst connector. The drainage catheter flaps are located at the distal end of the catheter. The flaps help prevent migration hereby helping the drainage catheter to remain in the desired position. The side ports, also located the distal end of the drainage catheter, these help assist in drainage of pancreatic fluid. The touhy borst connector allows connection of the drainage catheter to the drainage connection tube; it also allows the drainage catheter to be flushed. The drainage connection tube allows the drainage catheter to be connected to a drainage collection bag. In the middle of the drainage connecting tube is a three way stopcock; this allows a flow through the drainage connecting tube during the procedure. The nasal transfer tube enables the drainage catheter to be threaded through the oral cavity and out through the nostril. The drainage catheter contains radiopaque material which allows the user to ensure the drainage catheter is accurately positioned using fluoroscopically.

### **V. INDICATIONS FOR USE**

This device is used for temporary endoscopic drainage of the pancreatic duct through the nasal passage by use of an indwelling catheter.

The indications for use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. The subject and predicate device have the same intended use for ductal drainage.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE**

The subject device is substantially equivalent to the currently marketed predicate, Cook Zimmon Endoscopic Pancreatic Stent cleared under the following 510(k): K900923 cleared on October 26, 1990.

In brief, the subject device has the same intended use and technological characteristics as the predicate, Cook Zimmon Endoscopic Pancreatic Stent with respect to the following:

- Both devices have the same intended use for duct drainage.
- Both devices are for use in the pancreatic duct.
- Both devices share diameter size.
- Both devices share a material type
- Both devices have anti migration features.
- Both the drainage catheter of the subject device and the stent of the predicate device have side ports to assist drainage.
- Both devices are visible under fluoroscopy (radiopaque).
- Both devices are placed endoscopically over a wire guide.
- Both sets are compatible with 0.035” wire guides.
- Both devices are for professional use.
- Both devices are intended for single use only.
- Both devices are supplied sterile and are sterilised using ethylene oxide.

The following technological differences exist between the subject device and the Cook Zimmon Endoscopic Pancreatic Stent, the predicate device:

- i) Internal versus external drainage
- ii) Components supplied
- iii) Dimensions
- iv) Features-flaps
- v) Materials

Cook's Endoscopic Nasal Biliary Drainage Set which was cleared under 510(k) K896323 on April 09, 1990 is being used as a reference device for this 510k submission (reference device number one).

The subject device and the first reference device share the following characteristics;

- Both devices are used for external drainage.
- Both devices contain the following components; Drainage Catheter (with touhy-borst connector), Nasal Transfer Tube and Drainage Connecting Tube.
- Both devices share a common drainage catheter length (250cms).
- Both devices share common drainage catheter diameters 5Fr and 7Fr.
- Both devices share a common drainage catheter material.
- Both devices have a Nasal Transfer Tube component of the same material. Both are 50cms in length.
- Both devices share Drainage Connecting Tube material.

This legally marketed reference device provides technical information which helps address the safety and effectiveness of features which are different between the subject device and the predicate device.

Boston Scientific Corporation's Advanix™ Pancreatic Stent and Naviflex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers cleared under 510(k) K133700 on May 14, 2014 is being used as reference device number two for this 510k submission.

The subject device and the second reference device share the following characteristic;

Anti-migration features; both devices have flap features to help prevent migration.

This legally marketed reference device provides technical information which helps address the safety and effectiveness of a feature which is different between the subject device and the predicate device.

## **VII. PERFORMANCE DATA**

The biocompatibility evaluation for the Nasal Pancreatic Drainage Set was conducted in accordance with the FDA's *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* June 16,

2016 and *International Standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (ISO10993-1:2009).*

The following biocompatibility testing was successfully completed;

- Cytotoxicity
- Intracutaneous
- Sensitization
- Acute Systemic Toxicity
- Systemic Toxicity
- 4 week muscle implantation
- Genotoxicity – Mouse Lymphoma Assay
- Genotoxicity – Bacterial Reverse Mutation Study

A summary of the bench testing completed is detailed in **Table 5.1**.

Testing was successfully performed as per Cook Ireland’s design control system in line with 21 CFR 820.30 including FDA recognised standards where relevant. The results from performance testing demonstrated that the subject device will remain sterile and will perform as intended for its 3 year shelf life.

**Table 5.1: Summary of the Bench Testing Performed**

<b>Test</b>	<b>Acceptance Criteria</b>	<b>Result</b>
Dimensional Verification and Simulated Use Testing (Simulated use - Time Zero and post aging)	Dimensional verification as per the design parameters of the device. For simulated use testing the device performs in line with the instructions for use.	All acceptance criteria were met.  Pass
Drainage Catheter: Resistance to collapse, flow rate and tensile testing, (Time Zero and post aging)	<b>Resistance to Collapse</b> Testing Per EN 1617:1997 <sup>1</sup> . The test article does not collapse when exposed to a pressure not less than -10kPa for a period not less than 60 sec.  <b>Flow Rate</b>	All acceptance criteria were met.  Pass

Test	Acceptance Criteria	Result
	<p>Testing per EN 1618:1997<sup>2</sup>. Minimum flow rate of 4 ml/min.</p> <p><b>Tensile Testing</b> Testing per JIS T 3243<sup>3</sup>, EN 1618:1997<sup>2</sup> and per EN 1617:1997<sup>1</sup>.</p> <p>There shall no breaks and cracks when subjected to a force of 4.9 N (5 Fr and 7 Fr catheters).</p> <p>Minimum force of 10N (7 Fr catheters).</p>	
Leakage Testing	<p>Testing per EN 1618:1997<sup>2</sup>. At a test pressure of not less than 10kPa there is no leakage from the test articles including their connection to a drainage collection bag.</p>	<p>All acceptance criteria were met. Pass</p>
Radiopacity Testing	<p>Testing Per ASTM F640-12<sup>4</sup> The drainage catheter is visible under fluoroscopy.</p> <p>Visibility of the Drainage catheter is equal to or greater than the visibility of the user-defined standard.</p>	<p>All acceptance criteria were met. Pass</p>
MR Testing	<p><b>Magnetically Induced Displacement Force</b> Testing per ASTM F2052-15<sup>5</sup> Deflection Angle &lt; 45°</p> <p><b>Magnetically Induced Torque</b> Testing per ASTM F2213-06<sup>6</sup> (2011) <math>\tau_{mag} &lt; \tau_{grav}</math></p> <p><b>Electrical Conductivity</b> &lt;1 S/m</p>	<p>All acceptance criteria were met. Pass</p>

Test	Acceptance Criteria	Result
	<b>MR Image Artifacts</b> Testing per ASTM F2119-07 <sup>7</sup> (2013) For information only.	
Sterile Barrier - Package Integrity Testing (Time zero and post aging)	<b>Peel Strength</b> Tested as per ASTM F88/F88M-15 <sup>8</sup> . The peel strength of the pouch seal is $\geq$ 1.2N/15mm seal width. <b>Bubble Leak Test</b> Testing as per ASTM F2096-11 <sup>9</sup> . No stream of bubbles released from outer pouch during leak testing.	All acceptance criteria were met.  Pass

## VIII. CONCLUSIONS

Performance testing results (including bench, biocompatibility, packaging integrity and shelf life testing) meet the relevant test criteria as per the testing/standards listed above.

The non-clinical data obtained from performance testing supports the safety and efficacy of the subject device. It demonstrates that subject device will perform as intended in line with the instructions for use. The test methods used for evaluating different characteristics' effects on safety and effectiveness are acceptable; FDA recognised standards were referenced where relevant. The performance data supports the substantial equivalence of the Nasal Pancreatic Drainage Set to the predicate device.

1 EN 1617:1997, Sterile drainage catheters and accessory devices for single use

2 EN 1618:1997, Catheters other than intravascular catheters - Test methods for common properties

3 JIS T 3243:2011, Catheters and tubes designed for the biliary tract

4 ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use

5 ASTM F2052-15 Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment.

6 ASTM F2213-06 (2011) Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance environment.

7 ASTM F2119-07 (2013) Standard test method for evaluation of MR image artifacts from passive implants.

8 ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials.

9 ASTM F2096-11, Standard test method for detecting gross leaks in packaging by internal pressurization (bubble leak test)