July 6, 2018

Cook Ireland Ltd.
Jacinta Kilmartin
Regulatory Affairs Manager
O'Halloran Road, National Technology Park
Limerick
Ireland

Re: K180868
Trade/Device Name: Nasal Biliary Drainage Set, Liguory Nasal Biliary Drainage Set, Nagaraja Nasal Biliary Drainage Set, Leung Nasal Biliary Drainage Set
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: June 21, 2018
Received: June 25, 2018

Dear Jacinta Kilmartin:

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 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,

for
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

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)*
K180868

Device Name
Nasal Biliary Drainage Set, Liguory Nasal Biliary Drainage Set, Nagaraja Nasal Biliary Drainage Set, Leung Nasal Biliary Drainage Set

Indications for Use *(Describe)*
This device is used for temporary endoscopic drainage of the biliary 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.

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Section 5: 510(k) Summary

I. SUBMITTER

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Date Prepared: Jul 06, 2018

II. DEVICE

Trade Name of Device: Nasal Biliary Drainage Set, Liguory Nasal Biliary Drainage Set, Nagaraja Nasal Biliary Drainage Set, Leung Nasal Biliary Drainage Set

The model numbers are

ENBD-X,
ENBD-X-LIGUORY,
ENBD-X-LIGUORY-RT,
ENBD-X-NAG,
ENBD-X-LEUNG-Y.

The X in the model number denotes the catheter Fr size and the Y denotes the number of drainage ports on the catheter.

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 Endoscopic Nasal Biliary Drainage Set cleared under 510(k)
K896323 cleared on April 09, 1990

IV. DEVICE DESCRIPTION

The subject device consists of a drainage catheter, nasal transfer tube, drainage connecting tube and pigtail straightener (provided with drainage catheters which have a pigtail configuration at the distal end). The drainage catheter has anti-migration features, side ports and a touhy-borst connector. The anti-migration features (which include pigtails, duodenal loops and a curved tip) help prevent migration enabling the drainage catheter to remain in the desired position. The side ports, also located at the distal end of the drainage catheter assist in the drainage of bile. 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 biliary 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, drainage of the biliary duct through the nasal passage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed predicate, the Cook Endoscopic Nasal Biliary Drainage Set cleared under the following 510(k): K896323 cleared on April 09, 1990

In brief, the subject device has the same intended use and technological characteristics as the predicate Cook Endoscopic Nasal Biliary Drainage Set with respect to the following:

- Both devices have the same intended use for duct drainage.
- Both devices are used in the biliary duct.
- Both devices are used for external drainage via the nasal cavity.
- Both devices contain the following components; Drainage Catheter (with touhy-borst connector), Nasal Transfer Tube and Drainage Connecting Tube.
- The subject device is offered in a number of lengths; one length (250cm) matches that of the predicate.
- The following drainage catheter diameters are in common between the subject and predicate devices: 5, 6, 7, and 10 Fr.
- Certain models of the subject device share a common drainage catheter material with the predicate device. Radiopaque Polyethylene.
- Both drainage catheters have side ports to assist drainage.
- Both drainage catheters share types of anti- migration features.
- Both Nasal Transfer Tubes are composed of Polyvinylchloride and are 50cms in length.
- Both Drainage Connecting Tubes are composed of Polyvinyl chloride
- 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 Endoscopic Nasal Biliary Drainage Set, predicate device:

i) Components supplied
ii) Dimensions
iii) Features-Marker Bands, Number of Side Ports and Curved Tip Feature
iv) Drainage Catheter Materials

VII. PERFORMANCE DATA

The biocompatibility evaluation for the subject device 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).*

Testing performed included simulated use, dimensional verification, resistance to collapse, flow rate, tensile, leakage, radiopacity, testing (tensile and marker band attachment/ corrosion) post exposure to simulated gastric environment (in simulated bile), MRI and shelf life testing.

Testing was performed as per Cook Ireland's design control system.

VIII. CONCLUSIONS

The non-clinical data supports the safety of the subject device and demonstrates that the subject device is safe and effective and should perform as intended in the specified use conditions. This non-clinical data supports the substantial equivalence of the subject device to the predicate device.