May 9, 2022

Cook Ireland LTD
Kieran Casey,
Regulatory Affairs Specialist
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND

Re: K213946
Trade/Device Name: Compass BDS Biliary Stent
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: April 12, 2022
Received: April 15, 2022

Dear Kieran Casey:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) 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 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213946

Device Name
Compass BDS® Biliary Stent

Indications for Use *(Describe)*
Endoscopic biliary stent placement for biliary drainage of obstructed ducts that could be caused by common bile duct stones, malignant biliary obstruction, benign or malignant strictures or other obstructed biliary conditions requiring drainage.

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."

Section 5: 510(k) Summary

I. SUBMITTER

Cook Ireland Ltd.
O' Halloran Road
National Technology Park
Limerick
Ireland

Phone: +353 61 334440
Fax: +353 61 239293

Contact Persons:
Kieran Casey, Regulatory Affairs Specialist
Jane Kennedy, Lead Regulatory Engineer

Phone: +353 61 334440
Fax: +353 61 239293

Date Prepared: December 10th, 2021

II. DEVICE

Trade Name of Device:

- Compass BDS® Biliary Stent

Model numbers:

- CBBSO-7-5
- CBBSO-7-10
- CBBSO-7-15

Classification Name: Biliary catheter and accessories (21 CFR 876.5010)

Regulatory Class: Class: II, Sterile

Product Code: FGE

III. PREDICATE DEVICE

Predicate: The Zimmon biliary stent, cleared under K172044 on February 27th, 2018

IV. DEVICE DESCRIPTION

The Compass BDS® Biliary Stent includes double pigtails with double radiopaque marker bands. Compass BDS® Biliary Stents are recommended for use with Cook stent introducers (PC-7, PC-7E, and FS-PC-7).

The product code for Compass BDS® Biliary Stent is CBBSO-X-Y (CBBSO-7-5, CBBSO-7-10, CBBSO-7-15), where X denotes French size (Fr) and Y denotes the length in centimeters (cm). This product contains a stent and a pigtail straightener. The stent design allows the stent to be introduced on either side and the double-pigtails minimize migration, while side holes enhance biliary fluid drainage. It also has a tapered tip at both ends to facilitate smooth cannulation. The stent has two radiopaque bands on both ends for fluoroscopic visibility.

V. INDICATIONS FOR USE

Endoscopic biliary stent placement for biliary drainage of obstructed ducts that could be caused by common bile duct stones, malignant biliary obstruction, benign or malignant strictures or other obstructed biliary conditions requiring drainage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed device, Cook Zimmon biliary stent (7Fr ZSO), cleared under K172044 on February 27th, 2018

In brief, the subject device has the same technological characteristics as the predicate, with respect to the following:

- The subject device and predicate device are for use in the biliary duct.
- The subject device and predicate device have the same intended use
  - Biliary stents use to drain obstructed biliary ducts.
- The subject device and predicate device are intended for single use only.
- The subject device and predicate device are supplied sterile
- The subject device and predicate device are sterilised using ethylene oxide.
- The subject device and predicate device are for professional use only.
- The subject device and predicate device require a 0.035” wire guide and endoscope to perform the therapeutic procedure.

- The subject device and predicate device are placed within the body endoscopically using fluoroscopic monitoring.
- The subject device and predicate device are supplied as stent only with pigtail straightener.
- The subject device and predicate device are both double pigtail stents, both are made from Ethylene-Vinyl-Acetate (EVA) co-polymer and both contain multiple side ports with no flaps.

Differences between the predicate devices and subject devices can be summarized as follows:

- Stent marker bands
- Additional sideports
- Bidirectional stent ends

Reference devices cleared under K172044, K172057 and K180868 were used to support biocompatibility and reference devices cleared under K172044 and K172057 were used to support device performance.

VII. PERFORMANCE DATA

The biocompatibility evaluation for the subject device, was conducted in accordance with *ISO 10993-1: 2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"* and FDA's biocompatibility guidance, *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" (September 2020).* The following Biocompatibility tests were performed: Cytotoxicity, irritation, sensitization, acute systemic toxicity, systemic toxicity following subcutaneous implantation – 13 Week, muscle implantation study – 4 Week, muscle implantation study – 13 Week, mouse lymphoma assay, material mediated USP rabbit pyrogen study and bacterial reverse mutation study.
Testing was completed to Cook Ireland's design control system. Performance testing included simulated use, dimensional and visual testing, tensile strength testing, MRI conditional testing, radiopacity, flow rate and shelf-life testing.

VIII. CONCLUSIONS

The subject device has indications for use and technological characteristics that are similar to the predicate devices. The results of the non-clinical testing demonstrate that the subject device met the design input requirements based on the intended use, and do not raise new questions of safety or effectiveness. The results of these tests support a determination of substantial equivalence of the subject device to the predicate device.