June 14, 2024

Cook Ireland Ltd.
Casey Kieran
Senior Regulatory Scientist
O'Halloran Road
National Technology Park, Plassey
Limerick, V94 N8X2
Ireland

Re: K233079
Trade/Device Name: Zimmon® Pancreatic Stents/Stent sets;
Geenen® Pancreatic Stents/Stent Sets;
Geenen® Sof-Flex® Pancreatic Stent (GPSO-SF. GPSOS-SF);
Pushing Catheter and Guiding Catheter (GC, PC);
Johlin® Pancreatic Wedge Stent and Introducer Set (JPWS)

Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: May 14, 2024
Received: May 14, 2024

Dear Casey Kieran:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony Lee, 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)*
K233079

Device Name
Zimmon® Pancreatic Stents/Stent sets (SPSOF, SPSOS, ZEPDF, ZEPDS, ZPSOF, ZPSOS); Geenen® Pancreatic Stents/Stent Sets (GEPD, GPDS, GPSO, GPSOS); Geenen® Sof-Flex® Pancreatic Stent (GPSO-SF. GPSOS-SF); Johlin® Pancreatic Wedge Stent and Introducer Set (JPWS);Pushing Catheter and Guiding Catheter (GC, PC);

Indications for Use *(Describe)*
Zimmon® Pancreatic Stents/Stent sets (SPSOF, SPSOS, ZEPDF, ZEPDS, ZPSOF, ZPSOS); Geenen® Pancreatic Stents/ Stent Sets (GEPD, GPDS, GPSO, GPSOS); Geenen® Sof-Flex® Pancreatic Stent (GPSO-SF. GPSOS-SF):
Endoscopic pancreatic stent placement is used for pancreatic drainage that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, disrupted duct, fistula/pancreatic leak. Pancreatic stents are also used prophylactically for prevention of post-ERCP pancreatitis.

Johlin® Pancreatic Wedge Stent and Introducer Set (JPWS):
Endoscopic pancreatic stent placement for pancreatic drainage of obstructed ducts that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, and disrupted duct.

Pushing Catheter and Guiding Catheter (GC, PC):
These devices are indicated for use with biliary and pancreatic stents for the following indications.
For endoscopic biliary stent placement for biliary drainage of obstructed ducts that could be caused by common bile duct stones, malignant biliary obstruction and benign or malignant strictures.
For endoscopic pancreatic stent placement for pancreatic duct drainage that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, disrupted duct, fistula / pancreatic leak. Pancreatic stents are also used prophylactically for prevention of post-ERCP pancreatitis.

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.

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Section 5: 510(k) Summary

I. SUBMITTER

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Contact Persons:
Kieran Casey, Regulatory Affairs Team Lead
Orla Gibbon, Regulatory Affairs Manager

Date Prepared: 05 Jun 2024

II. DEVICE

Trade Name of Device:

- Zimmon® Pancreatic Stents/Stent sets,
- Geenen® Pancreatic Stents/Stent Sets,
- Geenen® Sof-Flex® Pancreatic Stent
- Pushing Catheter and Guiding Catheter,
- Johlin® Pancreatic Wedge Stent and Introducer Set

The model numbers are GEPD, GPDS, GPSO, GPSOS, GPSO-SF, GPSOS-SF, JPWS, SPSOF, SPSOS, ZEPDF, ZEPDS, ZPSOF, ZPSOS, GC and PC.

Common or Usual Name: Drainage Catheter
Classification Name: Biliary catheter and accessories
Regulation Number: (21 CFR 876.5010)
Regulatory Class: Class: II
Product Code: FGE

III. PREDICATE DEVICE

Predicate: Pancreatic Stents & Sets cleared under K172057

IV. DEVICE DESCRIPTION

The intended use of all Cook pancreatic stents and sets is to drain pancreatic ducts. A variety of stents in different sizes are available across the device range to accommodate various patient anatomies, the size and location of the obstruction and physician preference. They are offered in French sizes of between 3Fr and 11.5Fr, and in labelled lengths of between 2cm and 25cm.The subject devices and their components can be supplied as stent only, introducer only (guiding or pushing catheter) or as stent sets combining stent and introducers/introducer systems.

The stent sets can contain one or several of the following stent placement components; a flap protector, a guiding catheter, a pushing catheter or a dedicated introducer system. The flap protector is provided with stents that have duodenal flap-type anti-migration features, and is used to collapse the flap(s) on the device as it is introduced into the working channel of the endoscope. The function of the guiding catheter is to guide the pancreatic stent as part of its introduction to its intended location. The guiding catheter also has a Hub that allows for contrast injection. The function of the Pushing Catheter is to advance the stent, over a pre-positioned wire guide or Guiding Catheter, to its intended location within the anatomy, and to maintain the position of the Stent as it being deployed. The stents are polymeric and some of the stents have radiopaque bands. The stent designs include anti-migrational features such as duodenal pigtails, duodenal bends and ductal and duodenal flaps. To facilitate stent insertion and removal the stent ends are tapered or buffed. Side-ports on the pancreatic stents assist in drainage. All stents are deployed endoscopically over a guide wire in the same manner under fluoroscopic and endoscopic monitoring.
These Cook pancreatic stents and sets are all for professional use and are provided sterile. They are all intended for short-term use and have an indicated indwell of up to 3 months.

V. INDICATIONS FOR USE

Zimmon® Pancreatic Stents/Stent sets (SPSOF, SPSOS, ZEPDF, ZEPDS, ZPSOF, ZPSOS); Geenen® Pancreatic Stents/Stent Sets (GEPD, GPDS, GPSO, GPSOS); Geenen® Sof-Flex® Pancreatic Stent (GPSO-SF. GPSOS-SF): Endoscopic pancreatic

stent placement is used for pancreatic drainage that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, disrupted duct, fistula/pancreatic leak. Pancreatic stents are also used prophylactically for prevention of post-ERCP pancreatitis.

Johlin® Pancreatic Wedge Stent and Introducer Set (JPWS): Endoscopic pancreatic stent placement for pancreatic drainage of obstructed ducts that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, and disrupted duct.

Pushing Catheter and Guiding Catheter (GC, PC): These devices are indicated for use with biliary and pancreatic stents for the following indications. For endoscopic biliary stent placement for biliary drainage of obstructed ducts that could be caused by common bile duct stones, malignant biliary obstruction and benign or malignant strictures. For endoscopic pancreatic stent placement for pancreatic duct drainage that could be caused by pancreatitis, stricture, pancreatic cancer, anatomic anomalies of the pancreas, pancreatic fluid collection, pancreatic stones, disrupted duct, fistula / pancreatic leak. Pancreatic stents are also used prophylactically for prevention of post-ERCP pancreatitis.

There are minor differences in the indications for use statement compared to the subject 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 devices have the same intended use for drainage of pancreatic duct.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed device, the predicate device Pancreatic Stents and Sets cleared under K172057

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

- Both the subject devices and predicates share identical stent set components
- Both the subject device and predicates share identical stent dimensions
- Both the subject devices and predicates share identical design features such as anti – migration and side ports
- Both the subject devices and predicates share identical stent and introducer material types.

- Both the subject devices and predicates share identical introduction system dimensions
- Both subject devices and predicates have the same regulation number, regulation description, FDA classification code and class
- Both subject devices and predicates are used in the same anatomical site
- Both subject devices and predicates devices are sterile
- Both subject devices and predicates devices have the same sterilization method
- Both subject stents are visible under fluoroscopy
- Both subject devices and predicates devices have an identical atraumatic tip design
- Both subject devices and predicates devices are for professional use
- Both subject devices and predicate devices are single use
- Both subject devices and predicate devices have an identical method of placement and deployment

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

(i) expansion of the indications for use statement (ii) MRI compatibility (iii) Packaging configuration iv) Additional labelling

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)*.
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 devices.