DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 23, 2016

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

Re: K163018
Trade/Device Name: Zilver 635® Biliary Stent
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: October 27, 2016
Received: October 31, 2016

Dear Nora O'Connor:

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

John W. Sheets Jr -S

John W. Sheets Jr., Ph.D.
Director
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163018

Device Name
Zilver 635® Biliary Stent

Indications for Use *(Describe)*

This device is used in palliation of malignant neoplasms in the biliary tree

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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"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

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Date Prepared: October 27, 2016

II. DEVICE

Trade Name of Device: Zilver 635® Biliary Stent
The model numbers are ZILBS-635-6-4, ZILBS-635-6-6, ZILBS-635-6-8, ZILBS-635-6-10, ZILBS-635-6-12, ZILBS-635-8-4, ZILBS-635-8-6, ZILBS-635-8-8, ZILBS-635-8-10, ZILBS-635-8-12, ZILBS-635-10-4, ZILBS-635-10-6, ZILBS-635-10-8, ZILBS-635-10-10 and ZILBS-635-10-12

Common or Usual Name: Biliary Stent

Classification Name: Catheter, Biliary Diagnostic (21 CFR 876.5010)

Regulatory Class: II

Product Code: FGE

III. PREDICATE DEVICE

Primary Predicate: Zilver® 635™ Biliary Stent (ZIB6) cleared under the following 510(k)s:
K040505 cleared on Mar 16, 2004
K043481 cleared on Dec 29, 2004
K051124 cleared on July 12, 2005
K080037 cleared on Aug 01, 2008

Second Predicate: Zilver® Biliary Stent (ZILBS) cleared under the following 510(k):
K020788 cleared on May 08, 2002

IV. DEVICE DESCRIPTION

The Zilver 635® Biliary Stent (ZILBS-635) consists of the following two components: a self-expanding metal stent and stent delivery system. The stent is a laser cut self-expanding open-ended cylinder of nitinol. It is a slotted tube that is designed to provide support while allowing conformance to the duct upon deployment. Post-deployment, the stent is designed to impart an outward radial force upon the inner lumen of the duct, establishing patency in the stented region, thereby maintaining flow in the duct. The ZILBS-635 has radiopaque markers at both ends to assist in fluoroscopic visualization of the stent position. This stent delivery system like the predicate devices allows for co-axial deployment of the stent. The stent delivery system accepts a 0.035 inch wire guide. The stent delivery system includes a handle assembly and an introducer assembly. The handle assembly consists of a handle, a wire guide FLLA, holding bushing, a cannula, a check flo hub FLLA/cap and a safety tab. The introducer assembly consists of an outer sheath, an inner carrier and tip. The stent delivery system has an endoscopic pusher ring located on the inner carrier near the proximal end of the loaded stent. The outer sheath has a radiopaque maker band located within the wall of the outer sheath at the distal end. The stent delivery system is supplied with a syringe for flushing through the wire guide FLLA and the check flo hub FLLA.

V. INDICATIONS FOR USE

This device is used in palliation of malignant neoplasms in the biliary tree.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed primary predicate Zilver® 635™ Biliary Stent (ZIB6), cleared under the following 510(k)s:
K040505 cleared on Mar 16, 2004
K043481 cleared on Dec 29, 2004
K051124 cleared on July 12, 2005
K080037 cleared on Aug 01, 2008

In brief, the subject device has the same technological characteristics as the primary predicate ZIB6 with respect to the following:

- Both devices have the same intended use and indications for use.
- Both devices are for use in the biliary tree.
- Both devices allow single or overlapping in their stent placement configurations.
- Both devices are intended for single use only.
- Both devices are supplied with a syringe for flushing.
- Both devices are sold sterile and are sterilised using ethylene oxide.
- Both devices are visible under fluoroscopy (radiopaque).
- Both devices have 1 radiopaque marker band on the stent delivery system.
- Both stents are radiopaque.
- Both stents are composed of nitinol with gold radiopaque markers at both ends of the stent.
- Both stents are laser cut and self-expanding.
- Both stents are intended to be permanently implanted.
- The stent outer diameters of 6, 8 and 10 mm are within the predicate diameter range (4 mm to 14 mm).
- The stents lengths of 40, 60, 80, 100 and 120 mm are within the predicate length range (20 mm to 140 mm).
- Both stents are supplied preloaded on a 6 Fr stent delivery system.
- Both stents are deployed using a coaxial catheter system.
- Both stent delivery systems are compatible with 0.035” wire guides.

The following technological differences exist between the subject device and the ZIB6, primary predicate device:

i) Instructions for Stent Placement Configuration
ii) Method of Placement and Stent Delivery System Markers
iii) Stent Delivery System Introducer Dimensions (Length) and Compatibility

iv) Stent Delivery System and Syringe (Accessory) Materials
v) Stent Delivery System - Outer Sheath to Check-Flo Hub FLLA
vi) Stent Delivery System - Outer Sheath Middle Layer
vii) Syringe Volume

The subject device is substantially equivalent to the currently marketed second predicate Zilver® Biliary Stent (ZILBS), cleared under the following 510(k)s:
K020788 cleared on May 08, 2002

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

- Both devices have the same intended use and indications for use.
- Both devices are for use in the biliary tree.
- Both devices allow single or overlapping in their stent placement configurations.
- Both devices are placed endoscopically (using endoscopic and fluoroscopic techniques).
- Both devices are intended for single use only.
- Both devices are supplied with a syringe for flushing.
- Both devices are sold sterile and are sterilised using ethylene oxide.
- Both devices are visible under fluoroscopy (radiopaque).
- Both stents are radiopaque.
- Both stents are composed of nitinol with gold radiopaque markers at both ends of the stent.
- Both stents are laser cut and self-expanding.
- Both stents are intended to be permanently implanted.
- Both stents are available in outer diameters 6, 8 and 10 mm.
- Both stents come preloaded on the stent delivery system.
- Both stents are deployed using a coaxial catheter system.
- Both stent delivery systems are compatible with 0.035” wire guides.
- Both stent delivery systems have the same working length.
- Both stent delivery systems have a minimum duodenoscope accessory channel of 2.8 mm for placement of single or overlapping stents.

The following technological differences exist between the subject device and the ZILBS, second predicate device:

i) Instructions for Stent Placement Configuration
ii) Stent Delivery System Markers
iii) Stent Lengths
iv) Stent Delivery System - Introducer Dimensions (Outer Diameter) and Compatibility

v) Stent Delivery System and Syringe (Accessory) Materials
vi) Stent Delivery System - Outer Sheath to Check-Flo Hub FLLA Joint
vii) Stent Delivery System - Outer Sheath Middle Layer
viii) Syringe Volume

VII. PERFORMANCE DATA

The biocompatibility evaluation for the Zilver 635® Biliary Stent (ZILBS-635) 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 device specific guidance document was consulted in preparing this premarket submission, FDA's *Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents*, February 5, 1998. Performance testing such as simulated use, deployment testing, dimensional testing, joint strength testing, MRI and shelf life testing were performed as per Cook's design control system.

VIII. CONCLUSIONS

The non-clinical data supports the safety of the subject device and demonstrates that the Zilver 635® Biliary Stent (ZILBS-635) is safe and effective and should perform as intended in the specified use conditions. This non-clinical data supports the substantial equivalence of the Zilver 635® Biliary Stent (ZILBS-635) to the predicate devices.