DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 7, 2017

Cook Ireland Ltd.
Charlene Ryan
Regulatory Affairs Specialist
O Halloran Road, National Technology Park
Limerick
Ireland

Re: K163169
Trade/Device Name: Zilver® 518 and 635™ Biliary Stent
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: November 10, 2016
Received: November 14, 2016

Dear Charlene Ryan:

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 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)*
K163169

Device Name
Zilver® 518 and 635 ™ Biliary Stent

Indications for Use *(Describe)*
The Zilver 518 and 635 Biliary Stent are indicated for use 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 8: 510(k) Summary

I. SUBMITTER

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Date Prepared: November 8th ,2016

II. DEVICE

Trade Name of Device: Zilver® 518™ Biliary Stent
Zilver® 635™ Biliary Stent

The model number is ZIB5-XX-Y.Y-ZZ and ZIB6-XX-Y.Y-ZZ where YY denotes the stent diameter and ZZ denotes the stent length.

Prefix: ZIB5 and ZIB6

Common or Usual Name: Biliary Stent
Classification Name: Stent, Metallic, Expandable, Biliary Catheters and accessories (21 CFR 876.5010)

Regulatory Class: II

Product Code: FGE

III. PREDICATE DEVICE

Predicate: Zilver® 518™ Biliary Stent (ZIB5) cleared under the following 510(k)s:

Zilver® 518™ Biliary Stent (ZIB5):

K033348, on December 15th, 2003

K042518, on October 1st, 2004

K050698, on March 30th, 2005

Predicate: Zilver® 635™ Biliary Stent (ZIB6) cleared under the following 510(k)s:

Zilver® 635™ Biliary Stent (ZIB6):

K040505, on March 16th, 2004

K043481, on December 29th, 2004

K051124, on July 12th, 2005

The predicate devices detailed above have not been subject to a design related recall.

IV. DEVICE DESCRIPTION

The Zilver® 518 and 635™ Biliary Stent is a self-expandable stent made of nitinol. The special laser-cut pattern of the nitinol tube provides a construction with strong radial force and high flexibility. It is a slotted tube that is designed to provide support while maintaining flexibility in 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 constant flow in the duct. The stent has radiopaque markers (gold rivets) at both ends to assist in fluoroscopic visualization of the stent position. The delivery system for both ZIB5 and ZIB6 devices includes a handle assembly and an introducer catheter assembly. The Zilver® 518 and 635™ Biliary Stent is mounted on the inner catheter of the delivery system and is restrained by an outer sheath. The delivery system is used to deliver the stent to the appropriate location. The stent is deployed by retracting the outer sheath while holding the central metal cannula stationary. Full deployment of the stent occurs when the distal end of the sheath has been retracted past the proximal end of the stent.

The stent is placed using fluoroscopic and percutaneous techniques.

V. INDICATIONS FOR USE

The Zilver® 518™ and 635™ Biliary Stent are indicated for use in palliation of malignant neoplasms in the biliary tree.

VI. COMPARISON OF TECHNOLOGICAL CHARACETERISTICS WITH A PREDICTE DEVICE

The subject device is substantially equivalent to the currently marketed device, the Zilver® 518 and 635 ™ Biliary Stent (ZIB5/ZIB6), cleared under:

Zilver® 518™ Biliary Stent (ZIB5):
K033348, on December 15th, 2003
K042518, on October 1st, 2004
K050698, on March 30th, 2005

Zilver® 635™ Biliary Stent (ZIB6):
K040505, on March 16th, 2004
K043481, on December 29th, 2004
K051124, on July 12th, 2005

In brief,
The ZIB5 subject device is identical to/ within the range of the Zilver® 518™ Biliary Stent, cleared under K050698 , with respect to the following:

- Both devices have the same intended use
- Both devices are for use in the biliary tree
- The method of deployment for both devices is identical using a co-axial introducer system.
- Both devices are supplied with the stent pre-loaded onto an introducer system.
- The stent in both devices are placed using percutaneous and fluoroscopic techniques.
- Both devices contain radiopaque markers on the delivery system and the stent

- The stent placement configuration for both devices allow single and overlapping placement
- The stent material of both devices is composed of Nitinol with gold radiopaque markers.
- Both devices use a laser cut and self-expanding stent design.
- The stent diameters and lengths applicable are identical to both devices.
- The delivery system lengths available are identical to both devices
- Both delivery system outer diameter is 5Fr (1.67mm)
- Both delivery systems are compatible with a 0.018" wire guide
- Both devices are intended for single use only
- Both devices are supplied with a syringe of the same volume
- Both devices are intended for permanent implantation
- Both devices are supplied sterile
- The method of sterilisation is identical for both devices

The ZIB6 subject device is identical to/ within the range of the Zilver® 635™ Biliary Stent, cleared under K051124 , with respect to the following:

- Both devices have the same intended use
- Both devices are for use in the biliary tree
- The method of deployment for both devices is identical using a co-axial introducer system.
- Both devices are supplied with the stent pre-loaded onto an introducer system.
- The stent in both devices are placed using percutaneous and fluoroscopic techniques.
- Both devices contain radiopaque markers on the delivery system and the stent
- The stent placement configuration for both devices allow single and overlapping placement
- The stent material of both devices is composed of Nitinol with gold radiopaque markers.
- Both devices use a laser cut and self-expanding stent design.
- The stent diameters and lengths applicable are identical to both devices.
- The delivery system lengths available are identical to both devices
- Both delivery system outer diameter is 6Fr (2.0mm)
- Both delivery systems are compatible with a 0.035" wire guide
- Both devices are intended for single use only
- Both devices are supplied with a syringe of the same volume
- Both devices are intended for permanent implantation
- Both devices are supplied sterile
- The method of sterilisation is identical for both devices

The following differences exist between the subject devices (ZIB5/ZIB6) and the predicates, K050698 and K051124 respectively:

1) Material formulation modification of Acrylonitrile Butadiene Styrene.
2) MR Safe to MR Conditional
3) Consolidation of the Instructions for Use

VII. PERFORMANCE DATA

The biocompatibility evaluation for the ZIB5 and ZIB6 devices was conducted in accordance with *ISO 10993-1*: *2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"* as recognised by FDA and FDA's biocompatibility guidance, "*Use of International Standard ISO10993, Biological evaluation of Medical Devices Part 1: Evaluation and testing (June 16, 2016)*".

FDA issued guidance document "*Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*" issued on December 11th, 2014 was consulted in preparation for this premarket submission. MRI testing was conducted to evaluate the magnetic field interactions, radiofrequency induced heating and magnetic resonance image artifact for the ZIB5 and ZIB6 devices in accordance with ASTM F2052-15, ASTM F2213-06 (2011), ASTM F2182-11a and ASTM F2119-07 (2013) respectively.

The device specific guidance document was consulted in preparing this premarket submission, *Guidance for the content of premarket notifications for metal expandable Biliary stents.* Performance testing such as non clinical joint tensile testing was performed as per Cook Ireland's design control system; there is no impact to the original testing conducted on the predicate device as a result of this modification.

VIII. CONCLUSIONS

Non-clinical testing carried out on the device supports the substantial equivalence of the ZIB5 and ZIB6 product to the predicate device and provides a reasonable assurance of safety and effectiveness and should perform as intended in the specified use conditions.