November 16, 2018

Cook Ireland Ltd
Cathrina McHale
Regulatory Affairs Specialist
O' Halloran Rd, National Technology Park
Limerick
Ireland

Re: K182980
Trade/Device Name: Zilver® 518™ Biliary Stent and Zilver® 635™ Biliary Stent
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: October 26, 2018
Received: October 29, 2018

Dear Cathrina McHale:

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. 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 has not been established.

Furthermore, the indication for biliary use 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

William H. Maisel -S

William H. Maisel, MD, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182980

Device Name
Zilver® 518™ Biliary Stent and Zilver® 635™ Biliary Stent

Indications for Use *(Describe)*
The Zilver 518 and 635 Biliary Stents are intended for 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.

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:

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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 7: 510(k) Summary

I. SUBMITTER

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Date Prepared: October 26th, 2018

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. ***Table 7.1*** details the range of Zilver® 518 and 635™ Biliary Stent sizes.

Table 7.1: Zilver® 518 and 635™ Biliary Stent Sizes

Stent Outer Diameter (mm)	5 French (1.67mm)					6 French (2.0 mm)				
	Delivery System 40, 80 & 125 cm					Delivery System 40, 80 & 125 cm				
	Stent Length (mm)									
	20	30	40	60	80	20	30	40	60	80
4	x	x	x	x	x	x	x	x	x	x
5	x	x	x	x	x	x	x	x	x	x
6	x	x	x	x	x	x	x	x	x	x
7	x	x	x	x	x	x	x	x	x	x
8	x	x	x	x	x	x	x	x	x	x
9	x	x	x	x	x	x	x	x	x	x
10	x	x	x	x	x	x	x	x	x	x
12						x	x	x	x	x
14						x	x	x	x	x

Prefix: ZIB5 and ZIB6
Common or Usual Name: Biliary Stent
Classification Name: Biliary catheter and accessories (21 CFR 876.5010)
Regulatory Class: II
Product Code: FGE

III. PREDICATE DEVICE

K163169, Zilver® 518™ and 635™ Biliary Stent

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 intended for palliation of malignant neoplasms in the biliary tree.

VI. COMPARISON OF TECHNOLOGICAL CHARACETERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed device, the Zilver® 518™ and 635™ Biliary Stent (ZIB5/ZIB6), cleared under K163169 on February 07th, 2017. This submission describes changes to the instructions for use only. There is no change to the indications for use, design, or materials. No additional testing was required in relation to the modifications to the Instructions for Use.

VII. PERFORMANCE DATA

There were no device changes, therefore no additional testing was required to support the determination of substantial equivalence to the predicate devices.

VIII. CONCLUSIONS

The subject device, is substantially equivalent to the predicate device, the Zilver® 518™ and 635™ Biliary Stent (K163169).