February 27, 2018

Cook Ireland Ltd.
Jane Kennedy
Senior Regulatory Affairs Specialist
O'Halloran Road, National Technology Park
Limerick
Ireland

Re: K172044
Trade/Device Name: Cotton-Huibregtse® Biliary Stent, Cotton-Leung® Biliary Stent, Cotton-Leung® Sof-Flex® Biliary Stent, ST-2 Soehendra Tannenbaum® Biliary Stent, Zimmon® Biliary Stent, Cotton-Huibregtse® Biliary Stent Set, Cotton-Leung® Biliary Stent Set, Zimmon® Biliary Stent Set, Solus® Double Pigtail Stent with Introducer, Guiding Catheter, Pushing Catheter, Fusion® Pushing Catheter, Stent Introducer Set, Oasis® One Action Stent Introduction System, Fusion® Oasis® One Action Stent Introduction System, Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary Stent, Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: February 12, 2018
Received: February 12, 2018

Dear Jane Kennedy:

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. 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); 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.

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.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
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)*
K172044

Device Name
Cotton-Huibregtse® Biliary Stent, Cotton-Leung® Biliary Stent, Cotton-Leung® Sof-Flex® Biliary Stent, ST-2 Soehendra Tannenbaum® Biliary Stent, Zimmon® Biliary Stent, Cotton-Huibregtse® Biliary Stent Set, Cotton-Leung® Biliary Stent Set, Zimmon® Biliary Stent Set, Solus® Double Pigtail Stent with Introducer

Indications for Use *(Describe)*
These devices are used to drain obstructed biliary ducts

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

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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)*
K172044

Device Name
Guiding Catheter, Pushing Catheter, Fusion® Pushing Catheter, Stent Introducer Set, Oasis® One Action Stent Introduction System, Fusion® Oasis® One Action Stent Introduction System, Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary stent, Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.

Indications for Use *(Describe)*
The following devices are used for endoscopic biliary stent placement:
Guiding Catheter
Pushing Catheter
Fusion® Pushing catheter
Stent Introducer Set

The following devices (with preloaded stent , if applicable) are intended for endoscopic biliary stent placement to drain obstructed bile ducts:
Oasis® One Action Stent Introduction System
Fusion® Oasis® One Action Stent Introduction System
Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary stent.
Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.

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.

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Section 5: Revised 510(k) Summary

I. SUBMITTER

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Date Prepared: July 03, 2017

II. DEVICE

Trade Name of Device:

Stents only:

- Cotton-Huibregtse® Biliary Stent
- Cotton-Leung® Biliary Stent
- Cotton-Leung® Sof-Flex® Biliary Stent
- ST-2 Soehendra Tannenbaum® Biliary Stent
- Zimmon® Biliary Stent

Introducers only/Introduction systems:

- Guiding Catheter
- Pushing catheter
- Fusion® pushing catheter
- Stent Introducer Set
- Oasis® One Action Stent Introduction System
- Fusion® Oasis® One Action Stent Introduction System

Stent sets:

- Cotton-Huibregtse® Biliary Stent Set
- Cotton-Leung® Biliary Stent Set
- Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® biliary stent.
- Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.
- Zimmon® Biliary Stent Set
- Solus® Double Pigtail Stent with Introducer

Model Numbers:

The following are the prefixes and suffixes of each device family;

Stents only:

- Cotton-Huibregtse® Biliary Stent- Prefix (CHBSO-)
- Cotton-Leung® Biliary Stent- Prefix (CLSO-)
- Cotton-Leung® Sof-Flex® Biliary Stent- Prefix (CLSO-SF-)
- ST-2 Soehendra Tannenbaum® Biliary Stent- Prefix (TTSO-)
- Zimmon® Biliary Stent- Prefix (ZSO-)

Introducers only/Introduction systems:

- Guiding Catheter - Prefix (GC-)
- Pushing catheter - Prefix (PC-) and potential suffix(-E)
- Fusion® pushing catheter- Prefix (FS-PC-)
- Stent Introducer Set- Prefix (SIS-)
- Oasis® One Action Stent Introduction System-Prefix (OA-) and potential suffix (-E)
- Fusion® Oasis® One Action Stent Introduction System - Prefix (FS-OA-)

Stent sets:

- Cotton-Huibregtse® Biliary Stent Set- Prefix (CHBS-)
- Cotton-Leung® Biliary Stent Set- Prefix (CLBS-)
- Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary Stent- Prefix(OACL-)
- Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent - Prefix(OATS-)
- Zimmon® Biliary Stent Set –Prefix (ZEBD-)
- Solus® Double Pigtail Stent with Introducer-Prefix (ZSS-) and suffix(-RB)

Common or Usual Name: Biliary Stents / Sets, Biliary Introducers/Introduction Systems

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

Regulatory Class: II

Product Code: FGE

III. PREDICATE DEVICE

Predicate: The Zimmon biliary stent set, cleared under K851962 on December 17, 1985 and the Oasis® one action introduction system, cleared under K040151 on February 20, 2004.

IV. DEVICE DESCRIPTION

The intended use of all Cook biliary stents is to drain obstructed biliary 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 5Fr and 11.5Fr, and in labelled lengths of between 1cm and 21cm.The subject devices and their components can be supplied as stent only, introducer only (guiding or pushing catheter), introduction system (guiding and pushing catheter) or as stent sets combining stent and introducers/introduction systems.

The stent sets can contain one or several of the following stent placement components; a flap protector/ pigtail straightener, a guiding catheter, a pushing catheter or a dedicated introducer system. The flap protector/ pigtail straightener can be provided to aid in introduction of the device over the wire (pigtail stents) and introduced into the working channel of the endoscope. The function of the guiding catheter is to guide the 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. Some introducers / introduction systems have a port that will allow use of the device in a short wire configuration. The stents are polymeric with some of the stents have radiopaque bands. The stent designs include centre, duodenal and centre bend shapes and anti-migration features such as pigtails and flaps. To facilitate stent insertion and removal the stent ends are tapered or buffed. Side-ports on the stents assist in drainage. All stents are deployed endoscopically over a guide wire in the same manner under fluoroscopic and endoscopic monitoring.

Table 1 outlines the compatibility of Cook introducer/introduction systems with Cook biliary stents which are not supplied as part of sets.

Table 1: Compatible Cook Introducers/Introduction Systems for Cook Biliary Stents.

Device Family		**Cook Biliary Stents**				
		Cotton-Leung®		**Cotton-Huibregtse®**	**ST-2 Soehendra Tannenbaum®**	**Zimmon®**
		CLSO-SF	**CLSO**	**CHBSO**	**TTSO**	**ZSO**
Fusion® Pushing Catheter (FS-PC)		X	5Fr 7Fr	7Fr	X	5Fr 7Fr
Pushing Catheter (PC-E)		7Fr				
Pushing Catheter (PC)		√	√	√	√	√
Guiding Catheter (GC)	**5Fr**	10Fr	8.5Fr	8.5Fr	8.5Fr	X
	6Fr	X	10Fr 11.5Fr	10Fr 11.5Fr	10Fr 11.5Fr	
Stent Introduction System (SIS)		X	8.5Fr 10Fr 11.5Fr	8.5Fr 10Fr 11.5Fr	√	X
Oasis® Introduction System (OA)						
Fusion® Oasis® Introduction System (FS-OA)		10Fr	8.5Fr 10Fr	8.5Fr 10Fr	8.5Fr 10Fr	X
Oasis® Introduction System (OA-E)		X				

These Cook Biliary stents 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

The following devices are used to drain obstructed biliary ducts:
Cotton-Huibregtse® Biliary Stent
Cotton-Leung® Biliary Stent
Cotton-Leung® Sof-Flex® Biliary Stent
ST-2 Soehendra Tannenbaum® Biliary Stent
Zimmon® Biliary Stent
Cotton-Huibregtse® Biliary Stent Set
Cotton-Leung® Biliary Stent Set
Zimmon® Biliary Stent Set
Solus® Double Pigtail Stent with Introducer

The following devices are used for endoscopic biliary stent placement:
Guiding Catheter
Pushing Catheter
Fusion® Pushing catheter
Stent Introducer Set

The following devices (with preloaded stent, if applicable) are intended for endoscopic biliary stent placement to drain obstructed bile ducts:
Oasis® One Action Stent Introduction System
Fusion® Oasis® One Action Stent Introduction System
Oasis® One Action Stent Introduction System with preloaded Cotton-Leung® Biliary Stent.
Oasis® One Action Stent Introduction System with preloaded ST-2 Tannenbaum® Biliary Stent.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed device, Cook Zimmon biliary stent set, cleared under K851962 on December 17, 1985 and the Cook Oasis® one action introduction system, cleared under K040151 on February 20, 2004.

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

- The subject devices and predicate devices are for use in the biliary duct.
- The subject devices and predicate devices have the same intended use
    - Biliary stents and stent sets-to drain obstructed biliary ducts.

  - Biliary introducers and introduction systems- for placement of the biliary stents within the bile duct of the body.

- The subject devices and predicate devices are intended for single use only.
- The subject devices and predicate devices are supplied sterile
- The subject devices and predicate devices are sterilised using ethylene oxide.
- The subject devices and predicate devices are for professional use only.
- The subject devices and predicate devices require a 0.035" wire guide and endoscope to perform the therapeutic procedure.
- The subject devices and predicate devices are placed within the body endoscopically using fluoroscopic monitoring.

<u>Stent and stent sets</u>

- Stent shape is common with some subject devices and the predicate device – straight with pigtails (pigtail shaped).
- The subject devices and the predicate device have anti migration features.
- The subject devices and the predicate device have stent loading aids - pigtail straightener.
- Side port features are present on many of the subject devices and the predicate device - to support additional drainage in the biliary duct.
- The subject devices and predicate device are visible under fluoroscopy – stent material is radiopaque.
- The subject devices and predicate device have the common stent set components –stent, introducer or introduction system and stent loading aid.
- Many of the subject devices and the predicate device share the same material of composition.
- The subject devices and predicate device have common stent diameter sizes.
- The subject devices and predicate device have common stent lengths.

<u>Introducers and Introduction systems</u>

- Material in guiding catheter component of subject devices and predicate device is radiopaque.
- Radiopaque bands are present on guiding catheter component of subject devices and predicate device.
- Subject device introducers and introduction systems and predicate device have the similar components – guiding catheter, pushing catheter, Hub, IDE port.
- The pushing catheter component of the subject devices and the pushing catheter of predicate device have common diameter size and lengths.
- The guiding catheter component of the subject devices and the guiding catheter predicate device of the predicate device have common diameter sizes and lengths.

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

- Stent shape and anti-migration features.
- Drainage features
- Variations in introducer and introduction system components supplied.
- Variations in stent set components supplied.
- Variations in introducer materials.
- Variations in stent materials.
- Introducer/introduction system dimensions
- Stent dimensions.

There is no change to the safety or effectiveness of these subject devices when compared to the cleared predicate devices. Design validation and verifications activities (performance testing) performed support the performance, safety and effectiveness of these subject devices and demonstrate no change in the safety and effectiveness profile previously established with the predicate device.

VII. PERFORMANCE DATA

The biocompatibility evaluation for the Biliary Stent Devices and Introducers, was conducted in accordance with *ISO 10993-1: 2009 "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" (June 16, 2016).*
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 device. The results of the non-clinical testing demonstrates that the Biliary Stent devices and Introducers 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 Biliary Stent devices and Introducers to the predicate devices.