May 4, 2017

Cook Ireland Ltd.
Jacinta Kilmartin
Regulatory Affairs Manager
O’Halloran Road, National Technology Park
Limerick
Ireland

Re: K163468
Trade/Device Name: Evolution® Duodenal Stent System - Uncovered, Evolution®
Colonic Stent System - Uncovered
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: II
Product Code: MUM, MQR
Dated: April 4, 2017
Received: April 6, 2017

Dear Jacinta Kilmartin:

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.

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,

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
Indications for Use

510(k) Number (if known)
K163468

Device Name
Evolution® Duodenal Stent System- Uncovered, Evolution® Colonic Stent System - Uncovered

Indications for Use (Describe)

Evolution® Duodenal Stent System- Uncovered: This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

Evolution® Colonic Stent System- Uncovered: This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

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.
Section 5: 510(k) Summary

I. SUBMITTER

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Date Prepared: April 28, 2017

II. DEVICE

Trade Name of Device: Evolution® Duodenal Stent System – Uncovered
The model numbers are EVO-22-27-6-D, EVO-22-27-9-D, EVO-22-27-12-D
Common or Usual Name: Stent, Metallic, Expandable, Duodenal
Classification Name: Stent, Metallic, Expandable, Duodenal (21 CFR 878.3610)
Regulatory Class: II
Product Code: MUM

Trade Name of Device: Evolution® Colonic Stent System – Uncovered
The model numbers are EVO-25-30-6-C, EVO-25-30-8-C, EVO-25-30-10-C
Common or Usual Name: Stent, Colonic, Metallic, Expandable
Classification Name: Stent, Colonic, Metallic, Expandable (21 CFR 878.3610)
Regulatory Class: II
Product Code: MQR
III. PREDICATE DEVICE


The predicate devices detailed above have never been subject to a design related recall.

IV. DEVICE DESCRIPTION

The same device description applies to both the Evolution® Duodenal Stent System and the Evolution® Colonic Stent System.

Stent Description:
This flexible, self-expanding stent is constructed of nitinol wire. The stent diameter is increased at either end to help provide resistance to migration. The total length of the stent is indicated by radiopaque markers on the inner catheter, indicating the actual length of the stent at the nominal stent diameter.

Introduction System Description:
The stent is mounted on an inner catheter, which accepts a 0.035 inch wire guide and is constrained by an outer catheter. The handle allows for desheathing to deploy the stent and resheathing to recapture the stent during stent deployment.

V. INDICATIONS FOR USE

Evolution® Duodenal Stent System: This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

Evolution® Colonic Stent System: This device is used for palliative treatment of colonic obstruction or colonic strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

The intended use of the modified devices and their respective predicate devices are identical.
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The modified devices are substantially equivalent to the currently marketed predicate devices, the Evolution™ Duodenal Stent System, K101530 cleared March 29, 2011 and the Evolution™ Colonic Stent System, K113510 cleared May 17, 2012.

In brief, the modified devices are identical to their respective predicate devices with regard to the following:

- Stent dimensions
- Stent design
- Stent materials
- Introduction system dimensions
- Introduction system materials (excluding outer catheter)
- Shelf life
- Sterility (Ethylene oxide, EO)
- For single use
- For permanent implantation (stent)
- Principle of operation

The following technological differences exist between the modified device and the currently marketed predicate devices, the Evolution™ Duodenal Stent System (K101530) and the Evolution™ Colonic Stent System (K113510):

- Outer Catheter material formulation change.

VII. PERFORMANCE DATA

The biocompatibility evaluation for the material formulation change 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), the following tests were conducted:

- Cytotoxicity
- Irritation
- Sensitization

The device specific guidance document was consulted in preparing this premarket submission, Guidance for the content of premarket notifications for esophageal and tracheal prostheses.
issued April 28th, 1998. Performance testing was performed as per Cook’s design control system, the following tests were conducted:

- Simulated Use (Including Deployment, Recapture, Deployment Accuracy)
- Dimensional Testing
- Tensile Strength Testing

VIII. CONCLUSIONS

The non-clinical data supports the safety of the modified device and demonstrates that the Evolution® Duodenal Stent System – Uncovered and the Evolution® Colonic Stent System – Uncovered is safe and effective and should perform as intended in the specified use conditions. This non-clinical data supports the substantial equivalence of the Evolution® Duodenal Stent System – Uncovered and the Evolution® Colonic Stent System – Uncovered to their respective predicate devices.