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 21, 2016

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

Re: K162717
Trade/Device Name: Evolution® Esophageal Stent System - Partially Covered
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: II
Product Code: ESW
Dated: October 4, 2016
Received: October 6, 2016

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.

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,

Joyce M. Whang -S

for

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162717

Device Name
Evolution® Esophageal Stent System - Partially Covered

Indications for Use *(Describe)*

This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.

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.

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Section 5: 510(k) Summary

I. SUBMITTER

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Date Prepared: December 05, 2016

II. DEVICE

Trade Name of Device: Evolution® Esophageal Stent System – Partially Covered
The model numbers are EVO-20-25-8-E, EVO-20-25-10-E, EVO-20-25-12.5-E and EVO-20-25-15-E.

Common or Usual Name: Esophageal Stent

Classification Name: Esophageal Prosthesis (21 CFR 878.3610)

Regulatory Class: II

Product Code: ESW

III. PREDICATE DEVICE

Primary Predicate: Evolution™ Esophageal Stent System, K080359 cleared May 09, 2008.
Second Predicate: Evolution™ Esophageal Stent System – Fully Covered, K093619 cleared on June 17th, 2010.
The predicate devices detailed above have never been subject to a design related recall.

IV. DEVICE DESCRIPTION

The Evolution® Esophageal Stent System – Partially Covered consists of a self-expanding metal stent and a stent introduction system. The stent is provided pre-loaded in the introduction system. The handle allows for desheathing to deploy the stent and resheathing recapturing the stent during stent deployment.
The stent is woven from nitinol wire. The stent is formed with a flange at either end. The increased diameter of the stent at the stent ends helps provide resistance to migration. A silicone membrane applied to the stent covers the complete body of the stent along with part of both flanges. The covering is intended to reduce the risk of tissue ingrowth and provides a seal for tracheoesophageal fistulas. To aid in visibility under fluoroscopy there are four bands at either end of the stent. The stent has a lasso loop which can be used to reposition the stent during the initial placement procedure if desired. The device is supplied sterile, intended for single use only and is available for prescription use only. Use of this device is restricted to a trained healthcare professional.

V. INDICATIONS FOR USE

This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.

The intended use of the subject and predicate devices are identical.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed devices, the Evolution® Esophageal Stent System, K080359 cleared May 09, 2008 and the Evolution™ Esophageal Stent System – Fully Covered, K093619 cleared on June 17th, 2010.
In brief, the subject device is identical to/ within the range of the Evolution® Esophageal Stent System, K080359, primary predicate device, and the Evolution™ Esophageal Stent System – Fully Covered, K093619, with respect to the following:

- Stent material
- Stent dimensions
- Stent function
- Introduction system dimensions
- Introduction system materials
- Shelf life
- Principle of operation
- For professional use
- For single use
- Sterility (Ethylene oxide, EO)

The following technological differences exist between the subject device and the Evolution® Esophageal Stent System, K080359, primary predicate device, and the Evolution™ Esophageal Stent System – Fully Covered, K093619:

- Materials and configuration of the stent lasso loop.
- MRI Information

VII. PERFORMANCE DATA

The biocompatibility evaluation for the Evolution® Esophageal Stent System – Partially Covered 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
- Acute Systemic Toxicity

- Implantation (with Histopathology Report)

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,* the following tests were conducted for the subject device:

- Simulated Use (Including Deployment, Repositioning, Dimensional)
- Corrosion Testing
- Tensile Strength Testing
- Shelf Life Testing (Visual Inspection, Radial Force, Simulated Use, Tensile Strength)
- Visual Inspection
- Torque Testing
- MR Compatibility Testing

VIII. CONCLUSIONS

The non-clinical data supports the safety of the subject device and demonstrates that the Evolution® Esophageal Stent System – Partially Covered 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® Esophageal Stent System – Partially Covered to the predicate devices.