DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 1, 2017

Cook Ireland Ltd
Laura Graham
Regulatory Affairs Specialist
O'Halloran Road, National Technology Park
Limerick
Ireland

Re: K171619
Trade/Device Name: 14Fr Colon Decompression Set (CDSG)
Marcon Colon Decompression Set (CDSM)
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: FEG
Dated: May 31, 2017
Received: June 2, 2017

Dear Laura Graham:

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,

Charles Viviano -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)*
K171619

Device Name
14Fr Colon Decompression Set (CDSG)
Marcon Colon Decompression Set (CDSM)

Indications for Use *(Describe)*
This device is used for treatment of acute non-toxic megacolon, pseudo-obstruction (Ogilvie's syndrome) and colonic 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.

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: May 31, 2017

II. DEVICE

Trade Name of Device:

- 14Fr Colon Decompression Set (CDSG)
- Marcon Colon Decompression Set (CDSM)

The model numbers are CDSG-14-175, CDSM-7, CDSM-8.5 and CDSM-10.

Common or Usual Name: Colon Decompression Set

Classification Name: Gastrointestinal Tubes and Accessories (21 CFR 876.5980)

Regulatory Class: II

Product Code: FEG

III. PREDICATE DEVICE

Predicate: Cook Colon Decompression Set, K900035 cleared on March 07, 1990.

IV. DEVICE DESCRIPTION

14Fr Colon Decompression Set (CDSG)

The CDSG device consists of a colon decompression tube, guiding catheter and wire guide. The colon decompression tube is 14Fr in diameter with a length of 175cm. The device design includes side ports which allow for colon decompression. The device has connections to allow attachment to drainage collection bag or for the device to be flushed. The colon decompression tube, guiding catheter and wire guide can be observed fluoroscopically. The device is supplied sterile, intended for single use only. Use of this device is restricted to a trained healthcare professional.

Marcon Colon Decompression Set (CDSM)

The CDSM device consists of a colon decompression tube and wire guide. The colon decompression tube is supplied in a range of diameter options, 7Fr, 8.5Fr and 10Fr. The colon decompression tube has a length of 350cm. The device design includes side ports which allow for colon decompression. The device has connections to allow attachment to drainage collection bag or for the device to be flushed. The colon decompression tube and wireguide can be observed fluoroscopically. The colon decompression tube has a design feature (pigtail) at the distal end of the device which helps reduce migration. The device is supplied sterile, intended for single use only. Use of this device is restricted to a trained healthcare professional.

Wire Guide

The same wire guide is supplied with both the CDSG and CDSM devices; the wire guide has a flexible distal ball tip.

V. INDICATIONS FOR USE

This device is used for treatment of acute non-toxic megacolon, pseudo-obstruction (Ogilvie's syndrome) and colonic strictures.

The subject and predicate device are intended to be used for colon decompression.

The intended use is identical; however, the indications for use (patient population) are limited for the subject device compared to the original clearance for the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH A PREDICATE DEVICE

The subject device is substantially equivalent to the currently marketed device, Colon Decompression Sets, K900035 cleared on March 07, 1990.

In brief, the subject device has the same technological characteristics as the predicate Colon Decompression Sets, with respect to the following:

- Both devices have the same intended use for colon decompression.
- Both devices are for use in the colon.
- Both devices are intended for single use only.
- Both devices are sold sterile and are sterilised using ethylene oxide.
- Both devices are visible under fluoroscopy (radiopaque).
- Both devices have side ports.
- Both devices are placed over the 0.035in wire guide.
- Both devices are supplied with a wire guide with the same material and dimensions.

The following technological differences exist between the subject device and the predicate device, Cook Colon Decompression Sets;

- Method of placement (Via a Colonoscope) and supplied with of guiding catheter.
- Colon decompression tube dimensions (Diameter and Length) and sideport configuration
- Pigtail (For CDSM models only)
- Material

VII. PERFORMANCE DATA

The biocompatibility evaluation for the Colon Decompression Sets, 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).*
Performance testing included simulated use, dimensional testing, resistance to collapse, flow rate, tensile strength testing, dimensional and leakage tests, MR safety testing, radiopacity 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 Colon decompression sets 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 colon decompression sets to the predicate device.