Section 5.0 510(k) Summary

MAR 2 9 2011

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Phone:	353 61 334440
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Date:	March 24, 2011
Trade Name:	Evolution™ Duodenal Stent System
Common Name:	Stent, Metallic, Expandable, Duodenal
Classification Name:	Stent, Metallic, Expandable, Duodenal (21 CFR 878.3610, Product Code: MUM)
Predicate Devices:	Boston Scientific Wallstent® Enteral Endoprosthesis with Unistep™ Delivery System (K991056) Boston Scientific WallFlex™ Enteral Duodenal Stent System with Anchor Lock Delivery System (K062750)
Description of the Device:	Stent Description: This flexible, self-expanding stent is constructed of nitinol wire. The total length of the stent is indicated by radiopaque markers on the inner

	catheter, indicating the actual length of the stent at nominal stent diameter. The stent has flanges at both stent ends. Introducer 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. A pistol-grip delivery handle allows stent deployment or recapture.
Indications for use:	This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.
Comparison of Characteristics:	The Evolution™ Duodenal Stent System is substantially equivalent to the currently marketed predicate devices, the Boston Scientific Wallstent® Enteral Endoprosthesis with Unistep™ Delivery System (K991056), and the Boston Scientific WallFlex™ Enteral Duodenal Stent System with Anchor Lock Delivery System (K062750).
Performance Data:	Performance (bench and clinical) testing was carried out to determine the equivalence of the Evolution™ Duodenal Stent System to the predicate devices and to verify the safety and effectiveness of the device. The following bench tests were carried out: deployment force testing, expansion force testing, compression force testing, dimensional testing, corrosion testing, tensile strength testing and MRI testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Jacinta Kilmartin
Regulatory Affairs Specialist
Cook Ireland Ltd.
National Technology Park
O'Halloran Road
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IRELAND

MAR 29 2011

Re: K101530
Trade/Device Name: Evolution™ Duodenal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MUM
Dated: February 14, 2011
Received: February 16, 2011

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0 Indications for Use

510(k) Number (if known): K101530

Device Name: Evolution™ Duodenal Stent System

Indications for Use:

This device is used for palliative treatment of duodenal or gastric outlet obstruction and duodenal strictures caused by malignant neoplasms.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101530