DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 9, 2015

Covidien
Mr. Michael Koczocik
Product Specialist, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K152565
Trade/Device Name: Auto Suture™ Locking Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 1, 2015
Received: September 9, 2015

Dear Mr. Koczocik:

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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" (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 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 yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152565

Device Name

Auto Suture™ Locking Trocar

Indications for Use *(Describe)*

This device is used during laparoscopy, creating a point of entry for laparoscopic instruments into the abdominal cavity.

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.

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510(k) Summary

This 510(k) summary of data used to demonstrate substantial equivalence is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98

NAME:	COVIDIEN
ADDRESS:	60 Middletown Avenue North Haven, Connecticut 06473 USA
CONTACT PERSON:	Michael Koczocik Product Specialist, Regulatory Affairs
PHONE NUMBER:	(203) 492-6312
FAX NUMBER:	(203) 492-5029
DATE PREPARRED:	September 1, 2015
TRADE/PROPRIETARY NAME:	Auto Suture™ Locking Trocar
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories per 21 CFR § 876.1500
PRODUCT CODE:	GCJ
CLASSIFICATION PANEL NAME:	Gastroenterology and Urology
FDA PANEL NUMBER:	78
DEVICE CLASS:	Pursuant to 21 CFR § 876.1500 an endoscope and accessories is a Class II device
PREDICATE DEVICE(S):	Auto Suture™ Locking Trocar K912980
DEVICE DESCRIPTION:	The Auto Suture™ Locking Trocar is a sterile, single-use device designed for primary punctures during laparoscopy.
INTENDED USE:	This device is used during laparoscopy, creating a port of entry for laparoscopic instruments into the abdominal cavity.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED AND PREDICATE DEVICE(S)	The Auto Suture™ Locking Trocar is designed to provide a port of entry for laparoscopic instruments into the abdominal cavity. It consists of a two piece design; a housing cannula and an obturator. The housing consists of a duck bill valve to provide and air-tight seal for insertion and removal of instruments. The cannula contains a component at the distal end that expands laterally, enlarging the diameter of the sleeve to secure the trocar sleeve to the inner abdominal wall. The outer abdominal wall is secured by sliding the rubber ring toward the patient.
MATERIALS:	All components of the Auto Suture™ Locking Trocar are comprised of materials which are in accordance with ISO 10993-1
PERFORMANCE DATA:	Bench Performance testing was conducted to demonstrate that the Auto Suture™ Locking Trocar is substantially equivalent to the predicate device and performs as intended
CONCLUSION:	The change is sterilization from gamma radiation to Ethylene Oxide (EtO), and material change do not alter the performance of the device. The device is determined to be substantially equivalent to the predicate device (Auto Suture™ Locking Trocar K912980).