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

June 18, 2015

Covidien LLC
Ms. Rebecca Magnanimo
Regulatory Affairs Product Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K151356
Trade/Device Name: Spacemaker™ Pro Access and Dissector System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 18, 2015
Received: May 20, 2015

Dear Ms. Magnanimo:

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" (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,

Jennifer R. Stevenson -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

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)*

K151356

Device Name

Spacemaker™ Pro Access and Dissector System

Indications for Use *(Describe)*

The Spacemaker™ Pro dissection balloon is primarily indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space.

The Spacemaker™ Pro blunt tip trocar is intended for use in establishing a port of access for insertion of endoscopic instruments into the abdominal cavity or extraperitoneal space in abdominal and extraperitoneal surgery.

The Spacemaker™ Pro structural balloon trocar is primarily indicated for patients undergoing laparoscopic surgical procedures requiring a sealed port of access and/or tissue retraction. This is also indicated in patients undergoing laparoscopic surgery requiring a sealed port of access and/or tissue separation in extraperitoneal procedures, such as in hernia repair, lymphadenectomy or bladder neck suspension procedures.

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.

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510(k) Summary

SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA
CONTACT PERSON:	Rebecca Magnanimo Regulatory Affairs Product Specialist Covidien llc Phone: (203) 492-6479 Fax: (203) 492-5029 e-mail: Rebecca.magnanimo@covidien.com
DATE PREPARED:	05/18/15
PRODUCT CODE:	GCJ
REGULATION NUMBER:	21 CFR 876.1500
TRADE/PROPRIETARY NAME:	Spacemaker™ Pro Access and Dissector System
COMMON/USUAL NAME:	Access Dissection System
CLASSIFICATION NAME:	Endoscope and Accessories
PREDICATE DEVICES:	Spacemaker™ System (K042412)
DEVICE DESCRIPTION:	The Spacemaker™ Pro access and dissector system consists of combinations of three dissectors and two balloon access devices integrated into a single, modular device. There are a total of five Spacemaker™ Pro device combinations. ▪ Blunt tip trocar with round dissection balloon ▪ Blunt tip trocar with oval dissection balloon ▪ Blunt tip trocar with cylindrical dissection balloon ▪ Structural balloon trocar with round dissection balloon ▪ Structural balloon trocar with oval dissection balloon Each combination also includes two 5mm optical ports cleared under K112349, for use during the laparoscopic procedure, and also includes an Obturator accessory in a shorter length.
INTENDED USE	The Spacemaker™ Pro dissection balloon is primarily indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space. The Spacemaker™ Pro blunt tip trocar is intended for use in establishing a port of access for insertion of endoscopic instruments into the abdominal cavity or extraperitoneal space in abdominal and extraperitoneal surgery. The Spacemaker™ Pro structural balloon trocar is primarily indicated for patients undergoing laparoscopic surgical procedures requiring a sealed port of access and/or tissue

retraction. This is also indicated in patients undergoing laparoscopic surgery requiring a sealed port of access and/or tissue separation in extraperitoneal procedures, such as in hernia repair lymphadenectomy or bladder neck suspension procedures.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICES:

Modifications to design and materials of the current Spacemaker™ Plus Line (K042412) have created five new product codes to be launched as the proposed Spacemaker™ Pro Access and Dissection System.

The changes include use of alternate material to remove latex from fixation/anchoring balloons (blunt tip trocar products), increase length of cannulas/dissection cannulas, addition of a stopcock, changes to balloon geometry (length and width), addition of 5mm reducer to allow for device use with 5mm instruments and addition of a shorter length obturator previously sold separately.

Also a new cylindrical shaped balloon design will be offered to facilitate component separation by including a new cylindrical shaped design to the dissection balloon.

The proposed Spacemaker Pro will also include two 5mm Trocar ports (K112349).

The proposed Spacemaker Pro was evaluated for the following:

- Biocompatibility studies were conducted for the proposed device.
- Sterilization has been evaluated.
- Stability studies for the proposed device have been performed.
- Performance studies (in vitro and in vivo) were conducted to demonstrate that the proposed device, is substantially equivalent to the predicate device.

In vitro testing that supports the intended use of this device includes:

<u>In vitro Testing:</u>

- Visual Inspection
- Stopcock Insufflation/Desufflation
- Balloon Inflation Force and Deflation Force using Syringe
- Balloon Inflation and Deflation Force using a Bulb
- Seal Leak Resistance
- Instrument Insertion and Withdrawal Force for Seal System
- Pressure to Inflate Dissector Balloon
- Dissector Balloon Leak Test
- Dissector Obturator Insertion and Withdrawal Force into/from Dissector

- Dissector balloon insertion force into cannula and withdrawal force
- Obturator Insertion and Withdrawal Force into/from Cannula
- 10mm Laparoscope Insertion and Withdrawal Force into/from Cannula
- Dissector Balloon Acuity
- 5mm Laparoscope Insertion and Withdrawal from Dissector
- Dissector Balloon Integrity
- Cannula Balloon Integrity
- Dissector Balloon Deflation
- Oval Dissector's Perforated Sheath
- Blunt Tip Trocar Balloon Diameter Measurement

In-vivo testing that supports the intended use of the device includes:

<u>In vivo Testing:</u>

- Dissection/Dissector Clarity
- Dissector Balloon Integrity
- Force Required to Remove Dissector
- Cannula Leak Functional Performance
- Balloon Functional Performance
- Trocar Balloon Removal/Anchoring Force

CONCLUSION:

The results of testing demonstrate that the modified Spacemaker™ Pro Access and Dissector System is substantially equivalent to the legally marketed Spacemaker™ Plus System(K042412).