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

December 9, 2014

Covidien
% Ms. Mary Mellows
Senior Regulatory Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K142547
Trade/Device Name: Bluntport Blunt Trocar with Threaded Anchor 5mm-12mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 7, 2014
Received: November 10, 2014

Dear Ms. Mellows:

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,

David Krause -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)*
K142547

Device Name
Bluntport™ Blunt Trocar with Threaded Anchor 5mm-12mm

Indications for Use *(Describe)*

The BLUNTPORT™ Blunt Trocar with Threaded Anchor is intended for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K142547

510(k) Summary

This 510(k) summary information 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 §807.92.

SUBMITTER:	Covidien 60 Middletown Avenue North Haven, CT 06473 (203) 492-5284 (T)
CONTACT PERSON:	Mary Mellows Senior Specialist, Regulatory Affairs
DATE PREPARED:	November 7, 2014
TRADE/PROPRIETRY NAME:	Bluntport™ Blunt Trocar with Threaded Anchor 5mm-12mm
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories
FDA PANEL NUMBER:	78
PRODUCT CODE:	GCJ
CLASS CODE:	Pursuant to 21 CFR 876.1500, surgical trocar is a Class II device
LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCY IS CLAIMED:	Versaport™ V2 Bladeless Optical Trocar (K130435)

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REFERENCED DEVICES NOTED IN THIS SUBMISSION:

Auto Suture™ Modified Grip (K942885)
Endo GIA Radial Reload (K132493)
SILS Hand Instruments (K091869)

REASON FOR 510(K) SUBMISSION:

Obtain market clearance for Covidien's Bluntport™ Blunt Trocar with Threaded Anchor 5mm-12mm.

DEVICE DESCRIPTION:

The Bluntport™ with Threaded Anchor 5mm-12mm is a sterile, single use device used for abdominal access during laparoscopic procedures. The device consists of a cannula assembly, blunt-tipped obturator component and an anchoring assembly. The cannula assembly accommodates various size laparoscopic devices ranging from 5mm to 12mm in diameter while still maintaining pneumoperitoneum. The anchoring device provides stability of the cannula at the access site.

INTENDED USE:

Intended for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry.

TECHNICAL CHARACTERISTICS:

The Bluntport™ with Threaded Anchor 5mm-12mm is substantially equivalent and has not introduced any new features relative to the predicate or referenced devices. An anchoring assembly (K942885) has been incorporated to secure the cannula assembly against tissue.

	Bluntport™ Blunt Trocar with Threaded Anchor 5mm-12mm (Proposed Device)	**Predicate Versaport™ V2 Bladeless Optical Trocar (K130435)**
Technological/ Design Characteristics	Cannula Assembly Sleeve: Smooth Housing: Internal seal Obturator Component: Blunt-tipped dark blue acrylonitrile butadiene styrene (ABS) with solid proximal and distal ends Anchoring Device: White ABS housing with dark blue nylon screw	Cannula Assembly Sleeve: Smooth or Ribbed Housing: Same as proposed device Obturator Component: Bladeless 304 Stainless Steel and dark blue ABS with transparent window at distal end and scope retention member at proximal opening. Anchoring Assembly: None

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MATERIALS: All components of the blunt-tipped obturator component and cannula assembly are similar to the predicate device Versaport™ V2 Bladeless Optical Trocar (K130435). Components of the anchoring assembly are similar to the Auto Suture™ Modified Grip (K942885) and materials used in the anchoring assembly are also used in the Endo GIA Radial Reload (K132493) and the SILS Hand Instruments (K091869). All materials have been tested in accordance with ISO Standard 10993-1.

PERFORMANCE DATA: Design verification studies were conducted to demonstrate that the Bluntport™ with Threaded Anchor 5mm-12mm is safe and effective and performs as intended. Testing to support the intended use of this device includes:

- In Vitro
  - pneumoperitoneum leak rate
  - anchoring strength
  - anchor position adjustment
- Biocompatibility
  - cytoxicity
  - sensitization
  - intracutaneous Irritation
  - acute Systemic Toxicity

CONCLUSION: The result of these tests demonstrate that the Bluntport™ with Threaded Anchor 5mm-12mm is substantially equivalent to the predicate device and does not introduce additional risk to the patient.