JAN 2 6 2011

8. 510(K) SUMMARY

8.1 SUBMITTER/510(K) HOLDER

Advanced Surgical Concepts
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Bray, Co. Wicklow
Ireland
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8.2 CONSULTANT

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Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
USA
Contact Person: Jonathan Kahan
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8.3 ESTABLISHMENT REGISTRATION NUMBER:

9616720

8.4 DATE PREPARED:

January 3, 2011

8.5 DEVICE NAME & CLASSIFICATION

Proprietary Name:	ASC TriPort+ Laparoscopic Access Devices
Common/Usual Name:	Laparoscopic Accessory
Classification Name:	Endoscopic Accessory and Surgical Retractor (21 CFR 876.1500)
Classification Number:	Class II

8.6 PREDICATE DEVICE

TriPort & QuadPort Laparoscopic Access Devices (K101794)

8.7 DEVICE DESCRIPTION

The ASC TriPort+ Laparoscopic Access Device is, like the parent TriPort and QuadPort devices cleared by the FDA under K101794, a laparoscopic multi-instrument port which performs the following two functions.

- Retracting a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen at the same time during laparoscopic surgery.
- Ensuring that pneumoperitoneum is maintained in the abdomen during the surgical procedure, whether or not one or more laparoscopic instruments are passing through the device.

The ASC TriPort+ Laparoscopic Access Device is sterile and disposable. The proposed ASC TriPort+ Laparoscopic Access Device performs the same function as the TriPort and QuadPort parent devices.

Like the parent ASC TriPort Laparoscopic Access Device, the proposed ASC TriPort+ Laparoscopic Access Device is comprised of the following three components:

- An *introducer component*, which delivers the Distal Ring of the ASC TriPort+ through a pre-made incision, into the abdominal cavity.
- A *retractor component*, which retracts an abdominal incision to allow the passage of laparoscopic instruments.
- A *valve component* which maintains the pneumoperitoneum established for the surgical procedure.

The ASC TriPort+ Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery. The ASC TriPort+ Laparoscopic Access Device is identical in function to the ASC TriPort & QuadPort Laparoscopic Access Devices, which have been cleared for marketing under K101794.

The modifications made to the TriPort & QuadPort to produce the TriPort+ were made to improve the performance, ergonomics and cost of the system and are summarized as follows:

- A change in the configuration of valve sizes.
- The gel valves have been replaced with more standard valve mechanisms.
- A redesign and material change to the Boot to accommodate the new valves and to improve ease-of-use.
- The removal of the Retaining Clips.
- The addition of a foam guiding ring.
- The addition of printed gradations on the sleeve.
- A material change to the Removal Ring.
- A redesign of the Introducer.
- A redesign and material change to the Insufflation ports.
- Packaging redesign.

The changes made to the parent TriPort & QuadPort Laparoscopic Access Devices to produce the TriPort+ are minor and do not represent changes to its intended use, operating principles or mechanism of action for the device.

8.8 Intended Use

The ASC TriPort+ Laparoscopic Access Device is intended for use as multiple instrument and/or camera port during minimally-invasive abdominal laparoscopic surgery.

8.9 Technological Characteristics And Substantial Equivalence

The TriPort+ Laparoscopic Access Device provides an access path for multiple laparoscopic instruments through a small incision in the abdominal wall. Its function is identical to that of the parent TriPort & QuadPort Laparoscopic Access Devices (K101794).

The TriPort+ and the parent TriPort & QuadPort Laparoscopic Access Devices are laparoscopic instrument ports. Identically to the TriPort, the TriPort+ retracts an abdominal incision (12 – 25mm) to allow laparoscopic instruments to pass through into the abdomen, and maintain pneumoperitoneum in the abdomen during the surgical procedure, whether or not laparoscopic instruments are passing through the port.

Both the TriPort+ and the predicate QuadPort allow the option for the simultaneous introduction of up to four laparoscopic instruments through a single incision.

Like the predicate devices, the TriPort+ is a sterile, single-use (disposable) device. The use of the TriPort+ and the predicates are identical in that they facilitate the passage of laparoscopic instrumentation while maintaining pneumoperitoneum.

The insertion method for the TriPort+ is identical to that of the parent TriPort device, where the Distal Ring is inserted, using the supplied Introducer, through a pre-made incision.

8.10 Performance Testing

Biocompatibility and performance verification testing of the TriPort+ demonstrates that the modifications that are the subject of this notification do not raise new issues of safety or effectiveness. Validation testing of the TriPort+ in a porcine model enrolled clinicians with various levels of experience and expertise and demonstrated that the device functioned as intended, that the performance did not raise new issues of safety and effectiveness and that formal user training was not required.

8.11 Conclusions

Based on design verification testing of TriPort+, along with design validation testing in a porcine model and on a simulator, the TriPort+ fulfills prospectively defined design and performance requirements, and is therefore substantially equivalent to the TriPort & QuadPort Laparoscopic Access Devices (K101794).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Mr. Jonathan Kahan
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004

JAN 26 2011

Re: K110004
Trade/Device Name: ASC TriPort+ Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ, GCJ
Dated: January 03, 2010
Received: January 03, 2010

Dear Mr. Kahan:

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,

For Mark N. Melkerson
12/19/12

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ASC TriPort+ Laparoscopic Access Device

Indications For Use:

The ASC TriPort+ Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Prescription Use: X 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110004