K101794

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510(k) Summary
For the Advanced Surgical Concepts (ASC)
TriPort and QuadPort Laparoscopic Access Devices

(per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

Advanced Surgical Concepts
Unit 4 Sunnybank Centre
Upper Dargle Road
Bray, County Wicklow
Ireland

NOV 29 2010

Establishment Registration Number: 9616720

Contact Person: Tanya Kavanagh
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Date Prepared: November 29, 2010

2. DEVICE NAME

Proprietary Name:	ASC TriPort and QuadPort Laparoscopic Access Devices
Common/Usual Name:	Laparoscopic Accessory
Classification Name:	Endoscopic Accessory and Surgical Retractor (21 CFR 876.1500)
Product Code:	OTJ

3. PREDICATE DEVICES

- TriPort Laparoscopic Access Device subject of K073719
- R-Port II Laparoscopic Access Device subject of K073170
- R-Port Laparoscopic Access Device subject of K070158

4. DEVICE DESCRIPTION

Physical Description

TriPort Laparoscopic Access Device:

The modified ASC TriPort Laparoscopic Access Device, like the parent TriPort cleared by the FDA under K073719, is still comprised of the following three components:

- an *introducer component* which creates an abdominal incision (except in the case where the surgeon creates a Hasson cut-down incision) and delivers the Distal Ring of the ASC TriPort 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 modified ASC TriPort Laparoscopic Access Device is still intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery. The modified ASC TriPort Laparoscopic Access Device is identical in function to the parent device, which has been cleared for marketing under K073719.

The modifications made to the parent device labeling to produce the proposed TriPort Laparoscopic Access device informs users and patients that the device does not contain Natural Rubber Latex. Additionally the labelling has been revised to extend the shelf life from three months to three years as notified in the original 510(k) and to make the device safer and easier to use. The changes made to the parent TriPort Laparoscopic Access Device to produce the proposed TriPort are minor and do not represent modifications to the indications for use, operating principles, or mechanism of action for the device. Therefore, the 510(k) Premarket Notification for the modified Tri-Port Laparoscopic Access Device is appropriate for review as a Special 510(k).

Since the submission of the original 510(k) K073719, a number of additional non-significant modifications, which were the subject of letters to file, were made to the parent TriPort device as follows:

- A second insufflation valve was added to facilitate evacuation of electrocautery smoke.
- Retaining clips are no longer blue in color (colorant has been removed from the material formulation).
- Flange on insufflation valve was extended from a roughly circular shape of 6mm diameter to a roughly oval shape 7.5mm x 4.5mm to effect a more secure connection to the Boot.
- Modification to the labeling to include a three year shelf life.

In accordance with FDA Guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device," issued in 1997, these modifications are included in this Special 510(k).

QuadPort Laparoscopic Access Device:

The TriPort has additionally been modified resulting in the QuadPort device. The modifications to the TriPort comprise the following:

- A fourth valve was added to accommodate an additional laparoscopic instrument.
- The Boot is larger in diameter to accommodate the fourth instrument valve.
- An Introducer and Retaining Clips are not required.
- The Removal Ring is made from a different material (the same material as is used for the TriPort distal ring).

These modifications fulfill the requirements for Special 510(k): Device Modification as defined in "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance," issued in 1998.

How the Device Functions

The ASC TriPort and QuadPort Laparoscopic Access Devices are laparoscopic multi-instrument ports which perform the following two functions:

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

Scientific Concepts That Form the Basis for the Device

The ASC TriPort and QuadPort Laparoscopic Access Devices apply radial force upon the incision creating an aperture though which the laparoscopic instruments pass. The ability to remove the boot, allows the clinician to deliver specimens without removing the entire port, and with the QuadPort, generally without the need to extend the incision.

Significant Physical and Performance Characteristics of the Device, such as Device Design, Material Used, and Physical Properties

The physical design and performance of the modified TriPort is unchanged. Materials changes relate to substitution with materials already used for the TriPort. The physical properties of the QuadPort differ from the TriPort in that the diameter of the boot is increased, allowing space for the addition of a fourth port.

5. INTENDED USE/INDICATION FOR USE

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

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The ASC TriPort and QuadPort Laparoscopic Access Devices provide an access path for laparoscopic instruments through a small incision in the abdominal wall. Their function is identical to that of the parent ASC TriPort Laparoscopic Access Device (K073719).

Both the proposed ASC TriPort/QuadPort and the parent device are laparoscopic instrument access ports that are used to perform the same function as a trocar. They retract a small abdominal incision to allow laparoscopic instruments to pass through to the abdomen and maintain pneumoperitoneum in the abdomen during the surgical procedure, whether or not laparoscopic instruments are passing through them.

Both the proposed ASC TriPort/QuadPort and the parent device, allow for the simultaneous introduction of up to 4 laparoscopic instruments through a single incision.

Like the predicate devices, the ASC TriPort and QuadPort are sterile, single-use (disposable) devices. The use of the ASC TriPort/QuadPort and the predicates are identical in that they facilitate the passage of laparoscopic instrumentation while maintaining pneumoperitoneum. The insertion of the ASC TriPort and the parent device are identical and are made consistently and safely during laparoscopic surgery.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Biocompatibility and performance verification testing of the ASC 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 ASC QuadPort in a porcine model enrolled clinicians with various levels of experience and demonstrate that the QuadPort functioned as intended, the performance did not raise new issues of safety and effectiveness, and that formal user training was not required.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was submitted as the basis for determining substantial equivalence.

9. Summary of Other Information

Other information submitted for review included revised Instructions for Use and promotional materials for use in the US.

10. Conclusions Drawn From Non-clinical and Clinical Tests

Based on design verification testing of both the TriPort and QuadPort, along with the validation testing of the QuadPort in the porcine animal model, the modified TriPort and QuadPort fulfill prospectively defined design and performance requirements.

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

NOV 2 9 2010

Advanced Surgical Concepts
% Medical Device Consultants, Inc.
Ms. Rosina Robinson
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K101794
Trade/Device Name: ASC TriPort and QuadPort Laparoscopic Access Devices
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: November 09, 2010
Received: November 10, 2010

Dear Ms. Robinson:

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,

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

Enclosure

K101794

Indications for Use

NOV 2 9 2010

Special 510(k) Number (if known):

Device Name: ASC TriPort and QuadPort Laparoscopic Access Devices

Indications for Use:

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

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use____ (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101794