K073719

Special 510(k) Summary
For the Advanced Surgical Concepts (ASC)
TriPort Laparoscopic Access Device

1. SUBMITTER/510(K) HOLDER

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

JAN 29 2008

Establishment Registration Number: 9616720

Contact Person: Tanya Kavanagh
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Date Prepared: December 26, 2007

2. DEVICE NAME

Proprietary Name:	ASC TriPort Laparoscopic Access Device
Common/Usual Name:	Laparoscopic Accessory
Classification Name:	Endoscopic Accessory and Surgical Retractor

3. PREDICATE DEVICES

- R-Port II Laparoscopic Access Device subject of K073170
- R-Port Laparoscopic Access Device subject of K070158
- Taut Inc. ADAPt Laparoscopic Port and Accessory subject of K010007
- Ethicon Endopath III Trocar System subject of K032676
- ASC Ecotract Device subject of K010711

4. DEVICE DESCRIPTION

The ASC TriPort Laparoscopic Access Device is a laparoscopic multi-instrument port which performs the following two functions:

- It retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen at the same time during laparoscopic surgery

- It ensures that pneumoperitoneum is maintained in the abdomen during the surgical procedure, whether or not one or more laparoscopic instruments are passing through the TriPort

The ASC TriPort Laparoscopic Access Device is sterile and disposable. The proposed ASC TriPort Laparoscopic Access Device performs the same function as other legally marketed port systems and standard trocars.

Like the parent ASC R-Port II Laparoscopic Access Device, the proposed ASC TriPort Laparoscopic Access Device is 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 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 R-Port II Laparoscopic Access Device, which has been cleared for marketing under K073170.

The modifications made to the R-Port II to produce the Tri-Port Laparoscopic Access device were made to improve the performance and ergonomics of the system and are summarized as follows:

- The outer diameter of the distal ring of the ASC TriPort has been increased by 10.08 mm to allow it to be used in slightly larger incisions. A slightly larger incision improves access for multiple instruments and makes it easier for the surgeon to remove larger specimens. As a consequence of this change, the length of the Injector Plunger component of the Introducer was reduced by 18 mm thereby creating a larger area into which the larger TriPort distal ring can fit comfortably.
- In order to remove specimens that do not fit through the R-port II gel valve, it is necessary to remove the entire device from the incision and remove

specimens through the incision. The TriPort has been modified to include a removable valve section that when removed, allows specimens to pass through the incision. This design maintains wound protection because the part of the device containing the sleeve material is still in place, while not having to remove the entire device to allow specimen removal. After specimen removal, the removable part (valve) may be conveniently re-attached and the abdomen re-insufflated. In order to secure the removable valve section during surgery, a two-part Securing Clip, comprised of two identical self-mating half-rings, is clamped around the Outer Proximal Ring and the Boot to prevent them from separating. In order to remove the valve section, the Securing Clip must first be detached from the device by pulling the two halves apart. After specimen removal, the valve sections are reattached and the two halves of the Securing Clip are snapped back together.

- The Tri-Port has been modified to include three smaller separate valves which accommodate one instrument insertion per valve. Therefore, each valve allows insertion of one instrument each which can be manipulated independently without affecting the seal around the other instruments. This design feature of the TriPort minimizes gas loss and reduces friction between instruments. The parent R-port II allows insertion of multiple instruments but because all are inserted through the same gel valve, gas loss can occur depending on the extent of movement of the instruments. As a result of the change to the gel valves, the TriPort includes a straight piece of flexible tubing for insufflation.
- The TriPort gel housing (the "boot") is molded from Santoprene thermoplastic elastomer (TPE) which allows for a wider range of movement of inserted instruments because Santoprene TPE is more flexible than the Tecoflex polyurethane material used in the parent R-Port II device.

The changes made to the parent R-Port II Laparoscopic Access Device to produce the 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 proposed TriPort Laparoscopic Access Device is appropriate for review as a Special 510(k).

5. INTENDED 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The ASC TriPort Laparoscopic Access Device provides an access path for laparoscopic instruments through a small incision in the abdominal wall. Its function is identical to that of the parent ASC R-Port II Laparoscopic Access Device (K073170), the ASC R-Port (K070158). Its function is also similar to predicate trocars.

To deploy a trocar, the surgeon first creates a skin incision at the desired location on the patient's abdomen. The trocar then creates a path through to the abdominal cavity using its bladeless dissecting-tipped component which is rotated back and forth as it is advanced through the tissue layers by the surgeon. Once it has penetrated through to the abdominal cavity, the bladeless dissecting-tipped component is removed, leaving the rigid cannula within the incision. A single laparoscopic instrument, or camera, can now be passed through the cannula to gain access to the abdominal cavity for a surgical procedure. There is a valve system on the trocar to maintain pneumoperitoneum, whether an instrument is present within the trocar or not. Most laparoscopic procedures require a laparoscope and one or more instruments to be located within the abdominal cavity. Each trocar can only accommodate a single camera or instrument, therefore three or more trocars are usually needed for laparoscopic surgery, each within its own incision.

Both the proposed ASC TriPort and the parent ASC R-Port II Laparoscopic Access Devices are laparoscopic instrument access ports that are used to perform the same function as a trocar. The ASC TriPort both retracts a small abdominal incision to allow laparoscopic instruments to pass through to the abdomen, and maintains pneumoperitoneum in the abdomen during the surgical procedure, whether or not laparoscopic instruments are passing through the port.

Both the proposed ASC TriPort and the predicate ASC R-Port II Laparoscopic Access Device, allow for the simultaneous introduction of up to 3 laparoscopic instruments through a single incision.

Like the predicate devices, the ASC TriPort is a sterile, single-use (disposable) device. The use of the ASC TriPort 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 predicate R-Port II are identical and are made consistently and safely during laparoscopic surgery.

7. PERFORMANCE TESTING

Biocompatibility, verification and validation testing have been performed which demonstrate that the ASC TriPort Laparoscopic Access Device functions as intended and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2008

Advanced Surgical Concepts
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K073719
Trade/Device Name: ASC TriPort Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 26, 2007
Received: December 31, 2007

Dear Ms. McNamara-Cullinane:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Special 510(k) Number (if known): K073719

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__ (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)

Mark A Millerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073719