K073170

510(k) Summary
for the Advanced Surgical Concepts (ASC)
R-Port II Laparoscopic Access Device

1. SUBMITTER/510(K) HOLDER

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

DEC 0 3 2007

Establishment Registration Number: 9616720

Contact Person: Tanya Kavanagh
Telephone: 353-(0)1-2864777

Date Prepared: November 8, 2007

2. DEVICE NAME

Proprietary Name:	ASC R-Port II Laparoscopic Access Device
Common/Usual Name:	Laparoscopic Accessory
Classification Name:	Endoscopic Accessory and Surgical Retractor

3. PREDICATE DEVICES

- 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 Advanced Surgical Concepts (ASC) R-Port II Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery. The proposed ASC R-Port II Laparoscopic Access Device is identical in design to the R-Port Laparoscopic Access Device, which has been cleared for marketing under K070158. Two modifications have been made to the use of the proposed ASC R-Port II Laparoscopic Access device. ASC has made very minor

changes to the indications for use and the recommended method for delivery of the device although the design of the device is identical to the one described in K070158. The proposed ASC R-Port II Laparoscopic Access Device and the original R-Port Laparoscopic Access Device are otherwise identical in design, mechanism of action and operating principles.

The proposed ASC R-Port II Laparoscopic Access Device is a laparoscopic instrumentation access port that is used to perform the same function as other port systems and standard trocars. The original R-Port was offered with four different Introducer components for deployment but the proposed ASC R-Port II is offered with only one Introducer and a new delivery method. The new recommended delivery method for the proposed ASC R-Port II consists of initially insufflating the abdomen using a standard Verres Needle before creating the port incision. This is common practice with standard trocar insertions. In addition, as described in K070158, the ASC R-Port II can also be deployed after the creation of a Hasson cut-down incision. This type of incision is also commonly used for the deployment of standard trocars. The Distal Ring of the ASC R-Port II is delivered through the Hasson incision using the Introducer component of the ASC R-Port II which is the same Injector Introducer cleared for marketing under K070158.

The ASC R-Port II Laparoscopic Access Port is a sterile, disposable laparoscopic instrument port which performs two functions, as follows:

- It retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen
- It ensures that pneumoperitoneum is maintained in the abdomen during the surgical procedure whether or not a laparoscopic instrument is passing through the port

Like the predicate R-Port Laparoscopic Access Device, the ASC R-Port II Laparoscopic Access Device is comprised of the following:

- a retracting portion which retracts an abdominal incision to allow the passage of laparoscopic instruments
- a valve portion which maintains the pneumoperitoneum established for the surgical procedure

5. INTENDED USE

The ASC R-Port II 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 R-Port II provides an access path for laparoscopic instruments through a small incision in the abdominal wall identical to the function of the predicate ASC R-Port Laparoscopic Access Device (K070158) and similar to the predicate trocars. A standard trocar consists of a bladeless dissecting-tipped component for creating a small incision in an abdominal wall, and a rigid cannula, which keeps the small incision open, thereby providing an access path for laparoscopic instruments through the small incision in the abdominal wall. To deploy a trocar, a skin incision is created at the desired location in the patient's abdomen. The trocar creates its own incision through to the abdomen using its bladeless dissecting-tipped member which is rotated back and forth as it is advanced through the tissue layers. Once it has penetrated through to the abdomen, the bladeless dissecting-tipped member is removed, leaving the rigid cannula through which the laparoscopic instruments can be introduced. There is a valve system on the trocar to maintain pneumoperitoneum, whether an instrument is present in the trocar or not.

The proposed ASC R-Port II and the predicate ASC R-Port Laparoscopic Access Device are laparoscopic instrument access ports that are used to perform the same function as a trocar. The ASC R-Port II functions to both retract a small abdominal incision to allow laparoscopic instruments to pass through to the abdomen, and to maintain the pneumoperitoneum in the abdomen during the surgical procedure whether or not a laparoscopic instrument is passing through the port. The only difference between the proposed ASC R-Port II device and the predicate ASC R-Port Laparoscopic Access Device (K070158) is that the ASC R-Port II allows for insertion of multiple instruments or cameras at one time, and provides an additional method of delivery. Other than those modifications, the proposed ASC R-Port II and predicate ASC R-Port Laparoscopic Access Device are identical.

Like the predicate devices, the ASC R-Port II is a sterile, single-use device. The use of the ASC R-Port II and the predicates are identical in that they allow the passage of laparoscopic instrumentation while maintaining pneumoperitoneum. Although insertion of the ASC R-Port II and the predicate trocars differs, the ASC R-Port II insertion does not affect safety and effectiveness of the device incisions are made consistently and safely during laparoscopic surgery.

7. PERFORMANCE TESTING

Biocompatibility and verification testing have been performed which demonstrated that the ASC R-Port II 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

DEC 0 3 2007

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

Re: K073170
Trade/Device Name: ASC R-Port II Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: November 8, 2007
Received: November 13, 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

510(k) Number (if known):

Device Name: ASC R-Port II Laparoscopic Access Device

Indications for Use:

The ASC R-Port II 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)

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

510(k) Number K073170