K070158 P1 of 3

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

AUG 23 2007

1. SUBMITTER/510(K) HOLDER

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

Establishment Registration Number: 9616720

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

Date Prepared: January 15, 2007

2. DEVICE NAME

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

3. PREDICATE DEVICES

- Ethicon Endo-Surgery LLC BASX Bladeless Trocar subject of K062209
- 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 R-Port Laparoscopic Access Device (ASC R-Port) is a laparoscopic instrument access port that is used to perform the same function as a standard trocar. The ASC R-Port is offered with four different Introducer components which can be used to deploy the ASC R-Port. The surgeon will select the appropriate Introducer based on whether the first ASC R-Port, second or subsequent ASC R-Port is being introduced and the size of the instruments to be passed through the ASC R-Port.

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

- It retracts a small abdominal incision to allow laparoscopic instruments 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.

The ASC R-Port 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.

Deployment of the first ASC R-Port is accomplished using a Hasson cut-down incision. This is also common practice for the deployment of a first trocar. Deployment of the second and subsequent ASC R-Ports is very similar to the deployment of standard trocars in that the incision is created by a bladeless dissecting-tipped introducer which is removed following creation of the abdominal incision.

5. INTENDED USE

The ASC R-Port Laparoscopic Access Device is intended for use as an endoscopic instrument or camera port during minimally invasive abdominal laparoscopic surgery.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The ASC R-Port provides an access path for laparoscopic instruments through a small incision in the abdominal wall very similar to the function of 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 ASC R-Port is a laparoscopic instrument access port that is used to perform the same function as a trocar. The ASC R-Port 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 **first** ASC R-Port is deployed via a Hasson cut-down incision which is created at the desired location in the patient's abdomen. The ASC R-Port is delivered through this incision with a blunt "Hasson Hook Introducer". The **second** and **subsequent** ASC R-Ports are deployed via a skin incision created at the desired location in the patient's abdomen. The ASC R-Port is mounted to the relevant bladeless dissecting – tipped introducer (Injector Introducer or 5mm Hook Introducer or 12mm hook Introducer). The bladeless dissecting–tipped introducer creates its own incision through to the abdomen by rotating it back and forth as it is advanced through the tissue layers. Once it has penetrated through to the abdomen, the distal ring of the ASC R-Port is separated from the bladeless dissecting-tipped member. The bladeless dissecting-tipped member is now removed from the incision.

When the ASC R-Port is deployed, the Distal Ring and the Outer Proximal Ring are drawn as close together as the abdominal wall will allow. This sets up tension in the Retracting Sleeve between these two rings, and it is this tension that opens the incision and creates an access path for laparoscopic instruments. There is a valve system on the ASC R-Port to maintain pneumoperitoneum, whether an instrument is present in the ASC R-Port or not.

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

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

AUG 2 3 2007

Re: K070158
Trade/Device Name: ASC R-Port Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 6, 2007
Received: August 8, 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

for Deb Dansereau DG 8/23/07

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

Enclosure

K070158

Indications for Use

510(k) Number (if known): K070158

Device Name: ASC R-Port Laparoscopic Access Device

Indications for Use:

The ASC R-Port Laparoscopic Access Device is intended for use as an endoscopic instrument 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 K070158