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510(k) Summary
A-Lap™ Set, the A-Lap™ Retractor, and the EZaxess

Date: December 16, 2008

Submitter Information:

JAN - 2 2009

EZsurgical
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Device Identification

Trade Name:	A-Lap™ Retractor
Device Classification Name:	Retractor
Review Panel:	General & Plastic Surgery
Product Code:	GCJ
Regulation Number:	876.1500
Device Class:	II

Trade Name:	EZaxess
Device Classification Name:	Laparoscope, general & plastic surgery
Review Panel:	General & Plastic Surgery
Product Code:	GCJ
Regulation Number:	876.1500
Device Class:	II

Trade Name:	A-Lap™ Set
Device Classification Name:	Laparoscope, general & plastic surgery
Review Panel:	General & Plastic Surgery
Product Code:	GCJ
Regulation Number:	876.1500
Device Class:	II

Predicate devices:

The A-Lap™ Set, the A-Lap™ Retractor and EZaxess are substantially equivalent to the following predicate devices:

- Autosuture endoscopic Fan retractor (United States Surgical corporation); cleared under K914190.
- Autosuture Endo paddle retractor (Autosuture); 510(k) exempt.
- Autosuture Versaport Plus Bladeless Trocar (Tyco Healthcare Group); cleared under k081169.

Device Description:

The A Lap™ set is laparoscopic surgical device compose of two components:
A-Lap™ Retractor - a surgical retraction instrument used to move, retain or hold back internal organs in the operative region during laparoscopic surgery. The device purposes is to widen the access area to the treatment site (the surgical field), to grasp and retract the surrounding tissues, to maintain the resultant size of the access area and to secure the retracted tissue or organs by holding it away from the surgical site. The retraction is achieved by a 12 cm X 12 cm polyester mesh connected to stainless steel wires.
EZaxess - a laparoscopic port included a 170 mm long and 10mm in diameter bladeless trocar and flexible cannula (10cm long and 10mm in diameter). The device is used to create and maintain a port of entry during laparoscopic surgery.
The A Lap™ set is intended to be use for various laparoscopic surgical procedures, such as gynecologic, general, urologic and thoracic procedures. It is fully disposable and is intended for single use only.

Intended Use

The A-Lap™ Set, the A-Lap™ Retractor and EZaxess will be both distributed together as a set and distributed separately.

1. A-Lap™ set:
   The A-Lap™ set has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The set may be used in procedures to create and maintain a port of entry and for temporary retracting of tissue.

2. A-Lap™ retractor:
   The A-Lap™ retractor has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The device may be used in procedures requiring temporary retracting of tissue.

3. EZaxess :
   The EZaxess is intended for use in creating and maintaining a port of entry in gynecologic, general, urologic and thoracic procedures.

Technological Characteristics

The components of the A-Lap™ Set, the A-Lap™ Retractor and EZaxess are similar in basic materials, design, construction and performance to the predicate devices.

Safety and Performance Testing

Biocompatibility of the A-Lap™ Set, the A-Lap™ Retractor and EZaxess materials has been verified in accordance with ISO 10993-1. Biological evaluation of Medical Devices – Part 1. Materials test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device.

Design analysis, in vitro and in vivo data confirm the safety and effectiveness of the device and that the basic functional characteristics are substantially equivalent to the predicate devices cited. Device evaluation included flexibility & mechanical strength tests and mesh compliance.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, A-Lap™ Set, the A-Lap™ Retractor and EZaxess meets the minimum requirements that are considered adequate for intended use and is substantially equivalent in design, materials, principles of operation and indications for use to current commercially available retractors/trocar predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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JAN – 2 2009

Re: K082291
Trade/Device Name: A-Lap™ Set, A-Lap™ Retractor, EZaxess
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 18, 2008
Received: December 24, 2008

Dear Ms. Diamant – Porat:

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): K082291

Device Name: A-Lap™ Set

Indications for Use: The A-Lap™ set has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The set may be used in procedures to create and maintain a port of entry and for temporary retracting of tissue.

Prescription Use ___X___ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (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)

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

510(k) Number K082291

INDICATIONS FOR USE

510(k) Number (if known): K082291

Device Name: A-Lap™ Retractor

Indications for Use: The A-Lap™ retractor has application for use in the creation and maintenance of an operative cavity such as the gynecologic, general, urologic and thoracic procedures. The device may be used in procedures requiring temporary retracting of tissue.

Prescription Use ___X___ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (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)

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510(k) Number K082291

INDICATIONS FOR USE

510(k) Number (if known): K082291

Device Name: EZaxess

Indications for Use: The EZaxess is intended for use in creating and maintaining a port of entry in gynecologic, general, urologic and thoracic procedures.

Prescription Use ___X___ (Per 21 CFR 801.109 subpart D) OR Over the Counter Use_____ (21 CFR 801 Subpart C)

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510(k) Number K082291