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PART B: 510(k) SUMMARY

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

OCT 15 2007

Contact:

Katie Bray
RA Specialist/Biomedical Engineer
(480) 763-5300 (o)
(480) 763-6089 (f)
kbray@ascenths.com

Date of preparation: December 13, 2006

Name of device: Trade/Proprietary Name: Reprocessed Endoscopic Trocars and Cannulas
Classification Name: Laparoscope, general & plastic surgery, reprocessed

Predicate Device	510(k) Title	Manufacturer
K041795	Modification to Optical Separator	Applied Medical
K032889	Optical Separator	Applied Medical
K012884	Dilating Tip Obturator	Applied Medical
K012968	Trocar Seal	Applied Medical

Device description: Reprocessed Endoscopic Trocars and Cannulas are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery. Endoscopic trocars and cannulas are available in a variety of configurations and materials as well as trocar and cannula sets. Trocar seals vary between single-port and multi-port seals.

Bladed Trocars

Manufacturer	Description	Model
Applied Medical	11mm x 100mm Shielded Obturator with Universal Seal, non-threaded	C0638
Applied Medical	12mm x 100mm Shielded Obturator with Universal Seal, non-threaded	C0639
Applied Medical	11mm x 100mm Shielded Obturator with Universal Seal, threaded	C0658
Applied Medical	12mm x 100mm Shielded Obturator with Universal Seal, threaded	C0659

Non-Bladed Trocars

Manufacturer	Description	Model
Applied Medical	12mm blunt tip trocar	C0718
Applied Medical	11mm blunt tip trocar	C0717
Applied Medical	12mm x 100mm Optical Separator system, handled, non-threaded	C0124
Applied Medical	12mm x 100mm Optical Separator system, handled, threaded	C0128
Applied Medical	12mm x 100mm Optical Separator system, non-handled, non-threaded	C0126
Applied Medical	12mm x 100mm Optical Separator system, non-handled, threaded	C0130
Applied Medical	11mm x 100mm Optical Separator system, handled, non-threaded	C0114
Applied Medical	11mm x 100mm Optical Separator system, handled, threaded	C0150
Applied Medical	11mm x 100mm Optical Separator system, non-handled, non-threaded	C0116
Applied Medical	11mm x 100mm Optical Separator system, non-handled, threaded	C0152
Applied Medical	8mm x 100mm Optical Separator system, non-threaded	C0675
Applied Medical	8mm x 100mm Optical Separator system, threaded	C0676
Applied Medical	15mm x 100mm Separator system with Universal seal, non-threaded	C0604
Applied Medical	15mm x 100mm Separator system with Universal seal, threaded	C0605
Applied Medical	12mm x 100mm Separator system with Universal seal, non-threaded	C0682
Applied Medical	12mm x 100mm Separator system with Universal seal, threaded	C0680
Applied Medical	11mm x 100mm Separator system with Universal seal, non-threaded	C0667
Applied Medical	11mm x 100mm Separator system with Universal seal, threaded	C0665
Applied Medical	12mm x 100mm Optical Separator, obturator, handled	C0120
Applied Medical	12mm x 100mm Optical Separator, obturator, non-handled	C0122
Applied Medical	12mm x 100mm Separator obturator	C0930
Applied Medical	11mm x 100mm Separator obturator	C0915
Applied Medical	5mm x 100mm Separator obturator	C0901
Applied Medical	5mm x 55mm Separator obturator	C0900

Stability Cones and Seals

Manufacturer	Description	Model
Applied Medical	10/11mm Conductive Stability Cone	C0704
Applied Medical	10/12mm Conductive Stability Cone	C0705
Applied Medical	12mm disposable non-conductive stability cone	C0707
Applied Medical	11mm disposable non-conductive stability cone	C0706
Applied Medical	12mm x 100mm cannula and Universal seal, non-threaded	C0632
Applied Medical	12mm x 100mm cannula and Universal seal, threaded	C0652
Applied Medical	11mm x 100mm cannula and Universal seal, non-threaded	C0631
Applied Medical	11mm x 100mm cannula and Universal seal, threaded	C0651
Applied Medical	Universal® Seals	C0600

Intended use: Reprocessed Endoscopic Trocars and Cannulas are intended for use during minimally invasive surgery for temporary dilation access to the abdominal and thoracic cavities for passage of diagnostic, therapeutic and operative instruments into the abdominal and thoracic cavities, and for percutaneous access to hollow body organs.

Indications statement: Reprocessed Endoscopic Trocars and Cannulas are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Technological characteristics:

The design, materials, and intended use of Reprocessed Endoscopic Trocars and Cannulas are identical to the predicate devices. The mechanism of action of Reprocessed Endoscopic Trocars and Cannulas is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions's reprocessing of Endoscopic Trocars and Cannulas includes removal of adherent visible soil and decontamination. Each individual Endoscopic Trocars and Cannulas is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Endoscopic Trocars and Cannulas. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Endoscopic Trocars and Cannulas perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Endoscopic Trocars and Cannulas) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascent Healthcare Solutions
% Ms. Katie Bray
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, Arizona 85044

OCT 15 2007

Re: K063788
Trade/Device Name: Reprocessed Endoscopic Trocars and Cannulas
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: October 3, 2007
Received: October 5 2007

Dear Ms. Bray:

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,

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

Enclosure

List of Devices:

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1. Indications for Use Statement

510(k) Number (if known):

Device Name: Reprocessed Endoscopic Trocars and Cannulas

Indications for Use: Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K063788