K062497

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PART B: 510(k) SUMMARY

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
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JAN 31 2007

Contact:

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Date of preparation: July 24, 2006

Name of device: Trade/Proprietary Name: Reprocessed Trocars
Classification Name: laparoscope, general & plastic surgery, reprocessed

Predicate Device	510(k) Title	Manufacturer
K032676	ENDOPATH III Bladeless Trocars	Ethicon
K043253	Vanguard Reprocessed Dilating Tip and Blunt Trocar (Ethicon)	Ascent Healthcare (Vanguard Medical)
K043594	Vanguard Reprocessed Bladed Trocar, Non-Bladed Trocar (US Surgical/AutoSuture Series)	Ascent Healthcare (Vanguard Medical)

List of Reprocessed Devices: The following list represents specific Trocars models that will be reprocessed by Ascent Healthcare Solutions:

Family	Cat. No.	Description	Sleeve Style	ID	Length
Ethicon-Endopath XCEL Trocar	B5ST	XCEL Bladeless Trocar	Stability	5mm	75mm
	B5SP	XCEL Bladeless Trocar	Smooth	5mm	75mm
	CB5SP	XCEL Cannula	Smooth	5mm	75mm
	CB5ST	XCEL Cannula	Stability	5mm	75mm
	B5LT	XCEL Bladeless Trocar	Stability	5mm	100mm
	B5LP	XCEL Bladeless Trocar	Smooth	5mm	100mm
	CB5LP	XCEL Cannula	Smooth	5mm	100mm
	CB5LT	XCEL Cannula	Stability	5mm	100mm

Device description: The reprocessed device has the same intended use as the original device and does not incorporate new technology, new materials, or design changes. The product code for the original device, GCJ, falls within 21 CFR §876.1500 for Endoscopes and Accessories.

An Endoscope and Accessory device is defined within the code as used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an

image to the user's eye. The accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices.[1] The Endoscopic Trocars and Cannulas specified in this submission are used in endoscopic procedures and are considered accessories to the endoscope.

Endoscopic Trocars and Cannulas are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery. Surgical 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.

Endoscopy generally pertains to the use of a surgical instrument in conjunction with an endoscope inserted into the same body cavity. The endoscope permits visual inspection, with or without magnification, of the interior of the body cavity and permits observation of the surgical instrument during an operation for therapeutic or diagnostic purposes.

Endoscopic surgery is conducted through a cannula that extends across the abdominal wall and provides channels where instruments, such as scopes, retractors and staplers, can be inserted to perform surgery. As part of this procedure, the abdominal cavity is inflated with an insufflation gas, such carbon dioxide, to maintain the abdomen in a distended state and provide increased instrument maneuvering capability within the cavity. Valves are typically provided in the trocars to form seals around the instruments to prevent leakage of the insufflation gas.

Indications statement: Reprocessed Endoscopic Trocars 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 Trocars are identical to the predicate devices. The mechanism of action of Reprocessed Trocars 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 reprocessing of Trocars includes removal of adherent visible soil and decontamination. Each individual Trocars 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 Trocars. This included the following tests:

- Biocompatibility

[1] 21 CFR 876.1500

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

Performance testing demonstrates that Reprocessed Trocars perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Trocars) 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. Moira Barton
10232 South 51st Street
Phoenix, Arizona 85044

Re: K062497
Trade/Device Name: Reprocessed Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NLM
Dated: November 29, 2006
Received: November 30, 2006

JAN 3 1 2007

Dear Ms. Barton:

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

K062497

2. Indications for Use Statement

510(k) Number (if known):

Device Name: Reprocessed Trocars

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

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