K100080

Page 1 of ②

SECTION 10: EXECUTIVE SUMMARY

MAR 19 2010

SUBMITTER INFORMATION:

Applicant	Ascent Healthcare Solutions 10232 South 51st Street Phoenix, Arizona 85044
Contact Person	Moira Barton-Varty Senior Director Regulatory Affairs 480.763.5300 (o) 480.763.5350 (f) mbarton@ascenths.com
Representative/Consultant	N/A
Establishment Registration Number	1056128
Address of Manufacturing Site	Ascent Healthcare Solutions 5307 Great Oak Drive Lakeland, FL 33815

DESCRIPTION OF THE REPROCESSED DEVICE:

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

The Trocar Cannula is available with a threaded sleeve with a 5mm inner diameter and 100mm length. The Cannula is equipped with a sealing system for maintenance of pneumoperitoneum during insertion and withdrawal of instruments and with a luer stopcock port for insufflation and desufflation of the operative cavity.

Trocar Obturator is available in bladeless configuration sized 5 mm.. Bladeless optical obturators are equipped with a clear tip and a video laparoscopy channel to allow trocar insertion under direct visual guidance and minimize the risk for internal injury

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

Device Trade or Proprietary Name:	Reprocessed Trocars
Device Common, Usual or Classification Name:	Laparoscope, General & Plastic Surgery, Reprocessed

Classification Information:

Class:	II
Panel:	Gastroenterology/Urology
Product Code:	NLM
Citation:	21 CFR §Section: 876.1500

INDICATIONS FOR USE

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

PRINCIPLES OF OPERATION

Minimally invasive operative techniques involve a number of stages that vary according to surgeon preference and training. The sites, sizes, and the number and type of trocars placed also vary with the procedure and surgeon preference. The first step is to establish pneumoperitoneum. Typically, a Veress needle is inserted through a small paraumbilical incision to initiate the pneumoperitoneum. To prevent visceral injury, the patient is positioned to displace the small bowel from the pelvis. The Veress needle is inserted pointing inferiorly and insufflation with carbon dioxide is begun until an intraperitoneal pressure of 12 to 18 mm Hg is attained. The needle is then removed and replaced with a trocar through which a video laparoscope is inserted. The peritoneal cavity is inspected to identify any injury caused by the initial insertions. Then the remaining trocars are placed under direct laparoscopic observation, minimizing the possibility of visceral injury. Different surgical instruments are then inserted through these access ports to perform the surgical procedure.

TABLE OF COMPARISON

The design of the reprocessed device is the same as the predicate device. The same standard mechanical design, sizes and materials are utilized. There are no changes to the claims, clinical applications, patient population, or performance specifications.

The information in this traditional 510(k) submission is consistent with the information submitted in K062497 for Reprocessed Trocars. K062497 included information for trocars that are limited to one (1) reprocessing cycle. This 510(k) includes data to demonstrate that the Trocars, models B5LT and CB5LT, can undergo two (2) reprocessing cycles without changing the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ascent Healthcare Solutions
% Ms. Moira Barton-Varty
Senior Director Regulatory Affairs
10232 South 51st Street
Phoenix, Arizona 85044

MAR 19 2010

Re: K100080
Trade/Device Name: Reprocessed Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NLM
Dated: January 11, 2010
Received: January 12, 2010

Dear Ms. Barton-Varty:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100080

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100080

SECTION 11: DEVICE DESCRIPTION

LIST OF REPROCESSED DEVICES

The following table describes the specific Trocar models that will be reprocessed by Ascent Healthcare Solutions:

Family	Cat. No.	Description	Sleeve Style	ID	Length
Ethicon ENDOPATH® XCEL™ Bladeless Trocars	B5LT	XCEL BladelessTrocar	Stability	5mm	100mm
	CB5LT	XCEL Cannula	Stability	5mm	100mm

Table 11.1 List of Reprocessed Trocars

PHYSICAL DESCRIPTION/SPECIFICATION

The Reprocessed Trocar (model B5LT) includes the ***Cannula*** and ***Obturator*** components and will be used as the master product for validation. Model CB5LT consist solely of the ***Cannula*** component. A ***Cannula*** is designed to provide an access port for endoscopic instruments during minimally invasive surgical procedures. The design features of the cannnula include:

- *Cannula sleeve* is available in stability configuration with a 5mm inner diameter and 100mm length;
- *Reprocessed stopcock valve* minimizes inadvertent opening/closing of the valve during surgery, reducing overall procedure time;
- *Instrument valve* maintains pneumoperitoneum during insertion and withdrawal of instruments.

The ***Obturator*** is designed for incision and separation of the abdominal wall to provide the access port for the cannula sleeve. The design features of the obturator include:

- *Distal tip* is bladeless. Non-bladed obturators require greater penetration force than bladed obturators, but pose less risk for visceral/vascular damage.
- *Tapered tip* of the trocar is clear, providing visibility of tissue layers when used with an endoscope during insertion.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100080