DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2007

MediSISS
% Ms. Brandi J. James
Director of Technical Services
2747 SW 6th Street
Redmond, Oregon 97756

Re: K012644 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: August 10, 2006
Received: August 14, 2006

Dear Ms. James:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on July 29, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices 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/dsma/dsmamain.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): K012644

Device Name:

Reprocessed Endoscopic/Laparoscopic Trocars and Cannulas

Indications for Use:

Reprocessed Trocars and Cannulas are intended to open and maintain a port of entry during endoscopic procedures.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K012644

Reprocessed Endoscopic/Laparoscopic Trocars and Cannulas found to be substantially equivalent:

Manufacturer	Model	Description	Diameter Size	Tip Configuration
AutoSuture	179094	VERSAPORT™ RPF* V2 RPF* V2 Trocar System, w/Radiolucent Sleeve	5mm	Bladed w/Shield
AutoSuture	179095P	VERSAPORT™ Plus V2 Trocar, w/Radiolucent Sleeve	11mm	Bladed w/Shield
Ethicon	355L	ENDOPATH TRISTAR Trocar w/Stability Sleeve	5mm	Bladed w/Shield
Ethicon	512B	ENDOPATH TRISTAR Blunt Tip Bladeless Trocar	12mm	Blunt
Ethicon	355LD	ENDOPATH Dilating Tip Trocar, w/Stability Sleeve	5mm	Bladed w/Shield
Ethicon	355SD	ENDOPATH Dilating Tip Trocar w/Stability Sleeve	5mm	Bladed w/Shield
Ethicon	512SD	ENDOPATH Dilating Tip Trocar with Stability Sleeve	12mm	Bladed w/Shield
Ethicon	578SD	ENDOPATH Dilating Tip Trocar w/Stability Sleeve	7-8mm	Bladed w/Shield
Ethicon	511SD	ENDOPATH Dilating Tip Trocar w/Stability Sleeve	11mm	Bladed w/Shield
Ethicon	35HL	ENDOPATH Bladeless Trocar w/Smooth Sleeve, Handled	5mm	Blunt
Ethicon	35LNA	ENDOPATH Resposable Bladeless Trocar with Housing	5mm	Blunt
Ethicon	35NLT	ENDOPATH Bladeless Trocar with Stability Sleeve	5mm	Blunt
Ethicon	511H	ENDOPATH Bladeless Trocar w/Smooth Sleeve, Handled	11mm	Blunt
Ethicon	511NT	ENDOPATH, Bladeless Trocar w/Stability Sleeve	11mm	Blunt
Ethicon	511O	ENDOPATH, Bladeless Trocar, w/Smooth Sleeve	11mm	Blunt
Ethicon	512HA	ENDOPATH Resposable Bladeless Obturator and Housing, Handled	12mm	Blunt
Ethicon	35LST	ENDOPATH, Integrated Stability Trocar Sleeve	5mm	Cannula Only