K052299

2.0 510(K) SUMMARY FOR REPROCESSED ENDOSCOPIC TROCARS

MAY 2 3 2006

Submitter: SterilMed, Inc.

Contact Person:
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Date Prepared: August 22, 2005

Trade Name: Reprocessed Endoscopic Trocar

Classification Name: Laparoscope, General and Plastic Surgery

Classification Number: Class II 21CFR 876.1500

Product Code: NLM

Predicate Device(s): The Reprocessed Endoscopic Trocar is substantially equivalent to the SterilMed, Inc. Reprocessed endoscopic trocars (K043592 cleared on May 23, 2005) as well as the Endopath® XCEL™ Bladeless Trocar (K032676 cleared October 30, 2003) manufactured by Ethicon.

Device Description: The Reprocessed Endoscopic Trocar is a sterile instrument consisting of a radiolucent sleeve and obturator in sizes ranging from 75 to 150 mm in length and 5 to 12 mm in diameter. Reprocessed Endoscopic Trocars are devices that provide a pathway for entry of minimally invasive instruments to a body organ or cavity during abdominal, thoracic or gynecologic surgical procedures.

Intended Use:	The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures.
Functional and Safety Testing:	Representative samples of reprocessed endoscopic trocars underwent bench testing to demonstrate appropriate functional performance. Process validation testing was performed to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.
Conclusion:	The Reprocessed Endoscopic Trocar is substantially equivalent to the SterilMed, Inc. Reprocessed Endoscopic Trocars (K043592 cleared on May 23, 2005) as well as the Endopath® XCEL™ Bladeless Trocar (K032676 cleared October 30, 2003) manufactured by Ethicon. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2006

SterilMed, Inc.
% Mr. Dennis J. Toussaint
Director of Regulatory Affairs
11400 73rd Avenue North
Minneapolis, Minnesota 55369

Re: K052299
Trade/Device Name: Reprocessed Endoscopic Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: March 17, 2006
Received: March 20, 2006

Dear Mr. Toussaint:

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.

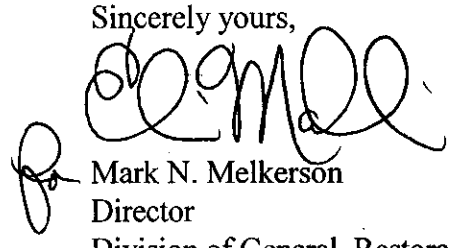
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

Reprocessed Endopath XCEL Bladeless Trocars found to be substantially equivalent:

MODEL	DESCRIPTION
B5LP	Smooth sleeve, 5mm diameter, 100mm length
B5LT	Stability sleeve, 5mm diameter, 100mm length
B5SP	Smooth sleeve, 5mm diameter, 75mm length
B5ST	Stability sleeve, 5mm diameter, 75mm length
B11LP	Smooth sleeve, 11mm diameter, 100mm length
B11LT	Stability sleeve, 11mm diameter, 100mm length
B12LP	Smooth sleeve, 12mm diameter, 100mm length
B12LT	Stability sleeve, 12mm diameter, 100mm length
B12SRT	Stability sleeve, 12mm diameter, 75mm length
H12LP	Stability sleeve, 12mm diameter, 100mm length

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INDICATIONS FOR USE

Device Name: Reprocessed Endoscopic Trocar

Indications for Use:

The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures.

Prescription Use __X__ 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 K052299