K070859

I. SUMMARY AND CERTIFICATION

A. 510(k) Summary

SEP 12 2007

Submitter: SterilMed, Inc.

Contact Person: Caroline Butterfield
11400 73rd Avenue North
Maple Grove, MN 55369
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Date Prepared: March 27, 2007

Trade Name: Reprocessed Ethicon ETS Endoscopic Linear Cutters

Classification Name: Staple, Implantable

Classification Number: Class II, 21 CFR 878.4750

Product Code: NLL

Predicate Devices:	The reprocessed Ethicon ETS Linear Cutters are substantially equivalent to the Ethicon Endopath ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter (K961390).
Device Description:	SterilMed's reprocessed Ethicon ETS Linear Cutter is a sterile, single patient use device. It delivers two double-staggered or two triple-staggered rows of staples while simultaneously dividing the tissue between the rows of staples. An articulation lever on the ETS-Flex Linear Cutter enables bilateral movement of the instrument jaws. These devices are reloadable linear cutters that allow for a maximum of 8 firings in a single surgical procedure. Note: Only the linear cutter is the subject of this submission, the implantable staple and the staple cartridge are not reprocessed and therefore are not included.
Intended Use:	The ETS 45, ETS-Flex 45, and ETS Compact-Flex 45 reprocessed, reloadable Ethicon Linear Cutters are intended for transection, resection and/or anastomosis. These instruments have applications in open and minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic and pediatric surgery. The ETS-Flex 45, ETS 45 and ETS Compact-Flex 45 device can be used with staple line or tissue buttressing materials such as bovine pericardium. The ETS, ETS-Flex (articulating) Endoscopic reprocessed, reloadable Linear Cutters (35mm) have applications in general, gynecological, and thoracic surgery for transection, resection, and/or creation of anastomoses.
Functional and Safety Testing:	Representative samples of reprocessed Linear Cutters are tested to demonstrate appropriate functional characteristics. Process validation testing is performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Conclusion:	The reprocessed ETS Linear Cutters are substantially equivalent to the Endopath ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter (K961390, K980023, K002398 and K020079) manufactured by Ethicon. This conclusion is based upon the devices' similarities in functional design (principle of operation), 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

SEP 12 2007

SterilMed, Inc.
% Mr. Dennis Toussaint
Director of Regulatory Affairs
11400 73rd Avenue North, Suite 100
Maple Grove, Minnesota 55369

Re: K070859
Trade/Device Name: Reprocessed Ethicon ETS Linear Cutters
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: NLL
Dated: August 27, 2007
Received: August 28, 2007

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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Indications for Use

510(k) Number (if known): K070859

Device Name: Reprocessed Ethicon ETS Linear Cutters

Indications for Use:

The ETS 45, ETS-Flex45, and Compact-Flex 45 reprocessed, reloadable Endoscopic Linear Cutters are intended for transection, resection and/or anastomosis. These instruments have applications in open and minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic and pediatric surgery. The ETS Flex 45, ETS 45 and ETS Compact Flex 45 device can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ETS and ETS-Flex (articulating) reprocessed, reloadable Endoscopic Linear Cutters (35mm) have applications in general, gynecologic, urologic, and thoracic surgery for transection, resection, and/or creation of anastomoses.

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 K070859

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Table 1 - List of Devices included in this Premarket Notification Submission

Manufacturer	Base Device	Model #	Description
Ethicon	ETS Flex 45	ATW45	ETS-Flex 45mm, 34cm long (no cartridge included)
		ATB45	ETS-Flex 45mm, 34cm long (no cartridge included)
		ATG45	ETS-Flex 45mm, 34cm long (no cartridge included)
		6TB45	ETS-Flex 45mm, 34cm long (no cartridge included)
	ETS Flex 35	ATW35	ETS-Flex 35mm, 34cm long (no cartridge included)
		ATB35	ETS-Flex 35mm, 34cm long (no cartridge included)
	ETS 45	TSW45	ETS Straight 45mm, 34cm long (no cartridge included)
		TSB45	ETS Straight 45mm, 34cm long (no cartridge included)
		TSG45	ETS Straight 45mm, 34cm long (no cartridge included)
	ETS 35	TSW35	ETS Straight 35mm, 34cm long (no cartridge included)
		TSB35	ETS Straight 35mm, 34cm long (no cartridge included)
	ETS Flex Compact 45	SCW45 Compact	ETS-Flex Compact 45mm, 24cm long (no cartridge included)
		SCB45 Compact	ETS-Flex Compact 45mm, 24cm long (no cartridge included)
		6CB45 Compact	ETS-Flex Compact 45mm, 24cm long (no cartridge included)
		SCG45 Compact	ETS-Flex Compact 45mm, 24cm long (no cartridge included)
		6SB45 Compact	ETS-Flex Compact 45mm, 34cm long (no cartridge included)