II. SUMMARY AND CERTIFICATION

OCT 18 2007

A. 510(k) Summary

Submitter: SterilMed, Inc.

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Date Prepared: March 30, 2007

Trade Name: Reprocessed AutoSuture GIA Endoscopic Staplers

Classification Name: Staple, Implantable

Classification Number: Class II, 21 CFR 878.4750

Product Code: NLL

Predicate Devices:	The reprocessed AutoSuture GIA Endoscopic Staplers are substantially equivalent to the AutoSuture GIA Endoscopic Stapler (K061095).
Device Description:	SterilMed's reprocessed AutoSuture GIA Endoscopic Stapler places two triple staggered rows of titanium staples and the blade, contained in the reload, simultaneously divides the tissue between the two rows. These devices allow for a maximum of 8 reloads in a single surgical procedure. The OEM has specified that the subject staplers may be fired up to 25 times in a single surgical procedure. SterilMed has lowered the number of firings allowed to 8 based upon clinical input, the procedures these devices are used for and the maximum allowable firings for similar devices of other manufactures. Note: Only the stapler is the subject of this submission, the implantable staple and the staple cartridge are not reprocessed and therefore are not included.
Intended Use:	The reprocessed reloadable AutoSuture GIA staplers are intended to be used in abdominal, gynecologic, pediatric and thoracic surgery for the resection, transection of tissue and for anastomosis. In addition the AutoSuture ENDO GIA Staplers may be used for transaction and resection of liver tissue, hepatic vasculature and biliary structures.
Functional and Safety Testing:	Representative samples of reprocessed staplers 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 endoscopic staplers are substantially equivalent to the GIA Endoscopic Stapler (K061095) manufactured by AutoSuture. 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

OCT 18 2007

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

Re: K070930
Trade/Device Name: Reprocessed AutoSuture GIA Endoscopic Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: NLL
Dated: October 10, 2007
Received: October 11, 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,

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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List of Devices Included in this Submission

OEM	Model	Description	Reprocessor	SterilMed Part Number
AutoSuture	030403	GIA Universal 12mm dia., 63 mm long shaft	SterilMed, Inc.	AUT030403
	030449	Endo GIA Universal 12mm dia., 155 mm long shaft		AUT030449
	EGIAUNIVXL	Endo GIA Universal XL – Long 12 mm dia., 255mm long shaft		AUTEGIAUNIVXL

Indications for Use

510(k) Number (if known):

Device Name: Reprocessed AutoSuture GIA Endoscopic Staplers

Indications For Use:
The Reprocessed Reloadable AutoSuture GIA staplers are intended to be used in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue and anastomosis. In addition the AutoSuture ENDO GIA Staplers may be used for transection and resection of liver tissue, hepatic vasculature and biliary structures.

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 K070930