DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2007

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

Re: K012598 - Supplemental Validation Submission
Trade/Device Name: Reprocessed Electric Instruments (Enclosed List)
Regulation Number: 21CFR878.4400
Regulation Name: Electrosurgical Device, Cutting & Coagulation & Accessories
Regulatory Class: II
Product Code: NUJ
Dated: August 8, 2001
Received: August 10, 2001

Dear Mr. Toussaint:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on October 23, 2000. 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
Intended Use form

INDICATIONS FOR USE PAGE (K012598)

(Same as currently cleared 510(k))

Device Name: Reprocessed Laparoscopic Electric Instruments

Indications for Use: Laparoscopic Electric Instruments are designed for use in minimally invasive procedures and open surgical procedures to facilitate coagulation, transection, resection, mobilization, and dissection of tissue.

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)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K012598

List of thirteen (13) Reprocessed Laparoscopic Electric Instruments of the SVS for K012598

Manufacturer	Model #	Description
AutoSuture	174301	Endo Mini-Shears, 5mm, Monopolar, 31cm
	174501	EndoShears, 5mm, Monopolar, 19cm
	174503	Endo Mini-Shears, 5mm, Monopolar, 19cm
	174505	Endo Dissect, 5mm Monopolar, 19cm
	176605	EndoSciz, 5mm, Monopolar, 31cm
	176643	EndoShears, 5mm, Monopolar, 31cm
	176645	EndoDissect, 5mm, Monopolar, 31cm
Ethicon	5DCS	Scissors, 5mm, Monopolar, 31cm
	5DCD	Dissector, 5mm, Monopolar, 31 cm
Everest (Gyrus)	3005	Cutting Forceps, 5mm, Bipolar, 33cm
	3025	Cutting Forceps, 5mm, Bipolar, 24cm
Gyrus	3005PK	Cutting Forceps, 5mm, Bipolar, 33cm
	3025PK	Cutting Forceps, 5mm, Bipolar, 24cm

SVS for K012598, Reprocessed Lap. Elec. Instruments

II. SUMMARY AND CERTIFICATION

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A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Dennis Toussaint
11400 73rd Avenue North
Maple Grove, MN 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: June 28, 2006

Trade Name: Reprocessed Laparoscopic Electric Instruments

Classification Name: Endoscopic Electrosurgical Accessory

Classification Number: Class II, 21 CFR 878.4400

Product Code: NUJ

Predicate Devices: The reprocessed laparoscopic electric instruments are substantially equivalent to BiCoag Forceps (K945975), manufactured by Everest; Endopath Endoscopic Instruments (K984240), manufactured by Ethicon; and counterpart devices from other original equipment manufacturers.

Device Description: Laparoscopic electric instruments are devices that are designed for use via laparoscopes or open surgical procedures. The devices have a handle, a rotating insulated shaft with a diameter of 5mm, a length of 19-33 cm and a distal tip. The distal tip of the devices consists of a variety of configurations including: dissectors, scissors and cutting forceps. The devices may be monopolar or bipolar and have a cautery connector on the handle or a connector cable. The device is connected via a cautery cable to a RF generator which provides electrical current to the device.

Intended Use: Laparoscopic electric instruments are designed for use in minimally invasive procedures and/or open surgical procedures to facilitate coagulation, transaction, resection, mobilization and dissection of tissue.

Functional and Safety Testing: Representative samples of reprocessed laparoscopic electric instruments underwent functional testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion: The reprocessed laparoscopic electric instruments are substantially equivalent to BiCoag Forceps (K945975), and Endopath Endoscopic Instruments (K984240), manufactured by Ethicon; and counterpart devices from other original equipment manufacturers.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.