K123096

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

JAN 2 5 2013

Submitter: Sterilmed, Inc.

Contact Person: Jason Skramsted
11400 73rd Avenue North
Maple Grove, MN 55369
Phone: 763-488-3483
Fax: 763-488-4491

Date Prepared: 01 October 2012

Trade Name: Reprocessed Vessel Sealers

Regulation Name: Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed

Regulation Number: 21 CFR 878.4400

Regulatory Class: Class II

Product Code: NUJ

Predicate Devices:	The reprocessed vessel sealers are substantially equivalent to the Covidien LigaSure™ Laparoscopic Instruments (K092879 and K031011).
Device Description:	The vessel sealers are electrosurgical instruments for use with the ForceTriad™ energy platform when performing laparoscopic procedures. The vessel sealers are capable of sealing vessels and lymphatics, grasping tissue and dissection. The vessel sealers have a 5 mm shaft diameter, 37 cm shaft length and a shaft rotation of 159 degrees. The distal end mechanism may have a blunt or dolphin nose tip.
Intended Use:	The reprocessed vessel sealers are indicated for use in general and gynecological, laparoscopic surgical procedures where ligation of vasculature is desired. The reprocessed vessel sealers can be used to seal vessels up to and including 7 mm, lymphatics, and tissue bundles. The reprocessed vessel sealers can also be used to seal pulmonary vasculature when used with the ForceTriad™ energy platform.
Technological Characteristics:	The reprocessed vessel sealers are identical to the predicate devices in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.
Functional and Safety Testing:	Representative samples of reprocessed vessel sealers were tested to demonstrate appropriate functional characteristics. Process validation testing was 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.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed vessel sealers to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed vessel sealers are safe, effective, and substantially equivalent to the predicate devices, Covidien LigaSure™ Laparoscopic Instruments (K092879 and K031011), as described in this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SterilMed, Incorporated
% Mr. Jason Skramsted
Regulatory Affairs Specialist
11400 73rd Avenue North
Maple Grove, Minnesota 55369

Letter dated: January 25, 2013

Re: K123096
Trade/Device Name: Reprocessed Vessel Sealers
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Skramsted:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Reprocessed Vessel Sealers

Indications for Use:

The reprocessed vessel sealers are indicated for use in general and gynecological, laparoscopic surgical procedures where ligation of vasculature is desired. The reprocessed vessel sealers can be used to seal vessels up to and including 7 mm, lymphatics, and tissue bundles. The reprocessed vessel sealers can also be used to seal pulmonary vasculature when used with the ForceTriad™ energy platform.

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)

Brian D. Pullin -S
2013.01.25 13:14:29 -05'00'

Division of Surgical Devices
510(k) Number: K123096