



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

January 15, 2016

Sterilmed Incorporated  
% Ming Cheng Chew  
Libra Medical  
8401 73rd Avenue North, Suite 63  
Brooklyn Park, Minnesota 55428

Re: K152134

Trade/Device Name: Reprocessed Vessel Sealer  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: NUJ  
Dated: December 15, 2015  
Received: December 16, 2015

Dear Ming Cheng Chew:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

  
Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Reprocessed Single-Use Device Models Included in Clearance:

<b>Device Model</b>	<b>Device Name</b>	<b>Original Manufacturer</b>
LF1737	Reprocessed LigaSure 5mm Maryland Jaw Sealer/Divider, 37cm shaft, used with ForceTriad energy platform	Covidien
LF1723	Reprocessed LigaSure 5mm Maryland Jaw Sealer/Divider, 23cm shaft, used with ForceTriad energy platform	Covidien

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
<b>Indications for Use</b>		
510(k) Number ( <i>if known</i> )		
K152134		
Device Name		
Reprocessed Vessel Sealers		
Includes the LF1737 and LF1723 models		
Indications for Use ( <i>describe</i> )		
<p>The reprocessed vessel sealer/dividers are bipolar electrosurgical instruments intended for use with the ForceTriad™ Energy Platform in general, minimally invasive and open surgical procedures where ligation and division of vessels and lymphatics is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymphatics) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.</p> <p>Indications for use include general open and minimally invasive procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.</p> <p>The reprocessed vessel sealer/dividers can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.</p>		
Type of Use ( <i>select one or both, as applicable</i> )		
<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D)		<input type="checkbox"/> Over-The-Counter Use (Part 21 CFR 801 Subpart C)
<b>CONTINUE ON A SEPARATE PAGE IF NEEDED</b>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995 *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff</p>		

*PRASStaff@fda.hhs.gov*

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K152134

**510(k) Summary**

<b>Submitter and Manufacturer:</b>	Patricia F. Kaufman Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446
<b>Manufacturing Facility Address:</b>	11400 73rd Avenue North Maple Grove, MN 55369
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<b>Secondary Contact:</b>	Julie Bodmer Libra Medical, Inc. Tel: 612-910-3412 Fax: 763-477-6357 Email: jbodmer@libramed.com
<b>Date of Submission:</b>	30 July 2015
<b>510(k) Number</b>	K152134
<b>Trade Name:</b>	Reprocessed Vessel Sealers
<b>Regulation Name:</b>	Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed
<b>Device Classification:</b>	Class II
<b>Device Regulation:</b>	878.4400
<b>Product Code:</b>	NUJ

<b>Predicate Device:</b>	Covidien LigaSure™ 5 mm, Maryland Jaw Sealer/Dividers (K133338).
<b>Device Description:</b>	The reprocessed vessel sealer is a sterile, hand-held bipolar RF electrosurgical instrument designed exclusively for use with the ForceTriad™ energy platform (generator) to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics clamped between the jaws, grasping tissue, and blunt dissection during general surgical procedures (as indicated), laparoscopic or open, using radio frequency (RF) energy. A hand actuated lever allows the user to open and close the instrument jaws without having to latch the lever, which includes a clicking mechanism that indicates to the user that the jaws are in the grasping zone, a button

	(switch) to activate the LigaSure™ mode by closing the handle against the button (switch) for vessel sealing, and a trigger to actuate an independent cutting blade.
Indications for Use:	<p>The reprocessed vessel sealer/dividers are bipolar electro-surgical instruments intended for use with the ForceTriad™ Energy Platform in general, minimally invasive and open surgical procedures where ligation and division of vessels and lymphatics is desired. The instrument creates a seal by application of RF electro-surgical energy to vascular structures (vessels and lymphatics) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.</p> <p>Indications for use include general open and minimally invasive procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of the vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.</p> <p>The reprocessed vessel sealer/dividers can be used on vessels and lymphatics up to and including 7 mm, and tissue bundles.</p>
Technological Characteristics:	The reprocessed vessel sealers have the same technological and performance characteristics as the predicates LF1723 and LF1737, K133338. Similar to the predicate models, each of these reprocessed devices seal vessels and lymphatics using radio frequency (RF) energy to achieve intended use and can mechanically divide the sealed areas or tissue with a mechanical cutting device.
Models Included in this Submission	<p><b>LF1737</b> - Reprocessed Covidien LigaSure™ 5mm Maryland Jaw Sealer/Divider, 37cm shaft, used with ForceTriad™ energy platform</p> <p><b>LF1723</b> - Reprocessed Covidien LigaSure™ 5mm Maryland Jaw Sealer/Divider, 23cm shaft, used with ForceTriad™ energy platform</p>
Functional and Safety Testing:	Representative samples of reprocessed devices 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 verification, ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf-life validation (ASTM 1980-07). In addition, validation of functional

	<p>performance (bench testing) was performed through visual inspection, and fatigue testing. Testing performed:</p> <ul style="list-style-type: none"> <li>• Electrical Safety</li> <li>• Device Functionality</li> <li>• Vessel Seal Burst (Static and Burst Pressure)</li> <li>• Vessel Seal Thermal Spread</li> <li>• EMC</li> <li>• Mold Stress</li> <li>• Drop</li> <li>• Spillage</li> <li>• Push</li> </ul> <p>Performance testing shows the reprocessed vessel sealers to perform as originally intended</p> <p>Biocompatibility testing for the following parameters were also performed:</p> <ul style="list-style-type: none"> <li>• Cytotoxicity</li> <li>• Pyrogen</li> <li>• Thrombogenicity</li> <li>• Irritation</li> <li>• Acute Toxicity</li> <li>• Immune Response</li> <li>• Hemolysis</li> <li>• Sensitization</li> </ul>
<p>Conclusion:</p>	<p>Sterilmed concludes that the reprocessed vessel sealers are safe, effective, and substantially equivalent to the predicate devices, Covidien LigaSure™ 5 mm, Maryland Jaw Sealer/Dividers Models LF1723 and LF1737 (K133338), as described in this premarket notification submission.</p>