DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 20, 2015

Sterilmed Incorporated
Ms. Julie Bodmer
Libra Medical
8401 73rd Ave North, Suite 63
Brooklyn Park, Minnesota 55448

Re: K143562
Trade/Device Name: Reprocessed Cordless Ultrasonic Dissection Device
Regulatory Class: Unclassified
Product Code: NLQ
Dated: April 10, 2015
Received: April 14, 2015

Dear Ms. Bodmer:

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" (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 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:

Device Model	Shaft Rotation	Shaft Diameter	Shaft Length
SCD13	360°	5 mm	13 cm
SCD26	360°	5 mm	26 cm
SCD396	360°	5 mm	39 cm

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143562

Device Name

Reprocessed Cordless Ultrasonic Dissection Device

Indications for Use *(Describe)*

The reprocessed cordless ultrasonic dissection devices are intended to be used for cutting soft tissue when control of bleeding and minimal thermal injury is desired. The devices can be used to coagulate isolated vessels up to 5 mm.

The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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6.0 510(K) SUMMARY

Submitter and Manufacturer:	Nicole Boser Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446
Manufacturing Facility Address:	11400 73rd Avenue North Maple Grove, MN 55369
Primary Contact:	Julie Bodmer Libra Medical, Inc. Tel: 612-910-3412 Fax: 763-477-6357 Email: jbodmer@libramed.com
Secondary Contact:	Nicole Boser Tel: (763) 488-3441 Fax: (763) 488-2050 Email: nboser@sterilmed.com
Date of Submission:	15 December 2014
Trade Name:	Reprocessed Cordless Ultrasonic Dissection Devices
Regulation Name:	Scalpel, Ultrasonic, Reprocessed
Device Classification:	Unclassified
Product Code:	NLQ

Predicate Devices:	Covidien Sonicision™ Cordless Ultrasonic Dissection Device, Model SCD396 (K101797). Covidien Sonicision™ Cordless Ultrasonic Dissection Device, Models SCD13 and SCD26 (K141371).
Device Description:	The cordless ultrasonic dissection devices are intended to be used to position, grasp, seal and dissect soft tissues, as well as providing control for functions such as selecting power levels, and blade placement and position. The instruments are used with a reusable generator, reusable battery pack and include a torque wrench as an accessory piece (the torque wrench is designed to ensure that the generator is properly secured to the device). The instruments have a 5 mm shaft diameter, 14.5 mm active blade, dual-mode energy button and are available in a variety of lengths. They can be used to coagulate vessels up to 5 mm and are designed to be inserted and extracted through a compatible 5mm trocar when used endoscopically.

Intended Use:	The reprocessed cordless ultrasonic dissection devices are intended to be used for cutting soft tissue when control of bleeding and minimal thermal injury is desired. The devices can be used to coagulate isolated vessels up to 5 mm. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.
Technological Characteristics:	The reprocessed cordless ultrasonic dissection devices are identical in technological and performance characteristics as the predicates, K101797 and K141371. There are no differences 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 cordless ultrasonic dissection 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, biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169), and shelf life validation (ASTM 1980). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, and fatigue testing. Testing performed: • Vessel Seal Thermal Spread • Vessel Seal Burst (Static and Burst Pressure) • Device Functionality • Pad Functionality • Pad Retention • Tissue Sticking • Torque Wrench Functionality Performance testing shows the reprocessed cordless ultrasonic dissection devices to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed cordless ultrasonic dissection devices are safe, effective, and substantially equivalent to the predicate devices, Covidien Sonicision™ Cordless Ultrasonic Dissection Device Model SCD396 (K101797) and Covidien Sonicision™ Cordless Ultrasonic Dissection Device Models SCD13 and SCD26 (K141371), as described in this premarket notification submission.