II. SUMMARY AND CERTIFICATION

K133414

A. 510(k) Summary

JAN 22 2014

Submitter: Sterilmed, Inc.

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Date Prepared: 06 November 2013

Trade Name: Reprocessed Closure Systems

Regulation Name: Laparoscope, General and Plastic Surgery, Reprocessed

Device Classification: Class II, 21 CFR 876.1500

Product Code: NLM

Predicate Devices:	The reprocessed closure systems are substantially equivalent to the Cooper Surgical Carter-Thomason CloseSure System® (K980123).
Device Description:	The closure system is a set of three components; consisting of one suture passer, one 5mm guide and one 10/12mm guide. The suture passer has a stainless steel shaft with a pointed tip that opens on one side to grasp the suture and a polycarbonate handle with a ring that actuates the tip. The 5mm and 10/12mm guides are made of polycarbonate with a cylindrical head on the proximal end connected to a shaft that tapers to a tip on the distal end. Each guide has two holes in the cylindrical head that pass through to opposite sides of the shaft. The holes allow the suture passer to be passed through the guide.
Intended Use:	The reprocessed closure systems are intended to pass sutures through soft tissue during endoscopic/laparoscopic surgery.
Technological Characteristics:	The reprocessed closure systems 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 closure systems 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 Part 18), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM 1980). 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 closure systems to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed closure systems are safe, effective, and substantially equivalent to the predicate devices, Cooper Surgical Carter-Thomason CloseSure System® (K980123), 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,RAC
Regulatory Affairs Specialist
11400 73rd Avenue North
Maple Grove, Minnesota 55369

January 22, 2014

Re: K133414
Trade/Device Name: Reprocessed Closure Systems
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NLM, GCJ, HCF, GEJ
Dated: November 6, 2013
Received: November 7, 2013

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 contact 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. 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,

Joshua C. Nipper -S

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

Enclosure

Indications for Use

510(k) Number (if known): K133414

Device Name: Reprocessed Closure Systems

Indications For Use:

The reprocessed closure systems are intended to pass sutures through soft tissue during endoscopic/laparoscopic surgery.

Prescription Use ___X____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K133414