K081814

II. SUMMARY AND CERTIFICATION

DEC 17 2008

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Joshua Clarin
11400 73rd Avenue North
Maple Grove, MN 55369
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Date Prepared: June 25, 2008

Trade Name: Reprocessed ENT Shavers

Classification Name: Ear, Nose and Throat Electrical or Pneumatic Surgical Drill

Classification Number: Class II, 21 CFR 874.4250

Product Code: ERL

Predicate Devices:	The reprocessed ENT shavers are substantially equivalent to Gyrus Diego® and Medtronic Xomed XPS® shavers.
Device Description:	SterilMed's reprocessed ENT shavers are powered dissectors inserted into a reusable hand piece and designed to be used in the removal of bone and tissue in various ENT, head and neck surgeries, and otoneurologic procedures. These devices were originally manufactured by Gyrus and Medtronic. Note: Only the shaver is the subject of this submission, the reusable hand piece and any other related equipment are not included in the scope of this submission.
Intended Use:	The reprocessed ENT shavers are intended to be used with a reusable hand piece and are designed for use in various ENT, head and neck surgeries, and otoneurologic procedures.
Functional and Safety Testing:	Representative samples of reprocessed ENT shavers 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.
Conclusion:	The reprocessed ENT shavers are substantially equivalent to Gyrus Diego® and Medtronic Xomed XPS® blades. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

B. Premarket Notification Statement

In lieu of a Premarket Notification Statement, a 510(k) Summary has been provided. Refer to Section II.A for 510(k) summary and certification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SterilMed, Inc.
c/o Dennis Toussaint
Director Regulatory Affairs
11400 73rd Avenue, N. Suite 100
Maple Grove, MN 55369

DEC 17 2008

Re: K081814
Trade/Device Name: Reprocessed ENT Shavers
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Toussaint:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081814

Indications for Use

510(k) Number (if known): K081814

Device Name: Reprocessed ENT Shavers

Indications for Use:
The reprocessed ENT shavers are intended to be used with a reusable hand piece and are designed for use in various ENT, head and neck surgeries and otoneurologic procedures.

Sinus Applications:

- Polypectomy
- Ethmoidectomy/Sphenoethmoidectomy
- Septoplasty
- Antrostomy
- Endoscopic DCR
- Frontal Sinus Trephination and Irrigation
- Frontal Sinus Drill Out
- Septal Spur Removal
- Trans-Sphenoidal Procedures

Head and Neck Procedures

- Rhinoplasty
- Lipodebridement in the Maxillary and Mandibular Region
- Soft Tissue Shaving
- Acoustic Neuroma Removal

Nasopharyngeal and Laryngeal Procedures

- Tonsillectomy
- Tracheal Procedures
- Adenoidectomy
- Laryngeal Lesion De-Bulking
- Laryngeal Polypectomy

Otology Procedures

- Mastoidotomy
- Mastoidectomy

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)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K081814

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List of Devices included in this Premarket Notification Submission - 510(k) K081814

Manufacturer	Model #
Gyrus	7013-8100
	7013-8000
	7013-8035
	7013-8001
	7013-8002
	7013-8003
Medtronic Xomed	18-84004HR
	18-84004
	18-83504HR
	18-83504
	18-82904HRE
	18-82904
	18-84002HRE
	18-84002
	18-83502HRE
	18-83502
	18-82902HRE
	18-82902
	18-84005HRE
	18-84005
	18-82905HRE
	18-82905
	18-82040HR
	18-82040
	18-82940HR
	18-82940