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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

NOV 0 8 2001

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
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Minneapolis, MN 55369
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Date Prepared: August 10, 2001

Trade Name: SterilMed Reprocessed Laser Probes

Classification Name: Laser, Ophthalmic

Classification Number: Class II, 21 CFR 886.4390

Product Code: HQF

Predicate Device(s): SterilMed's reprocessed laser probes are substantially equivalent to HGM Inc.'s Fleischman-Swartz Endo-Ocular Probe (K840590), and to the counterpart devices from the original manufacturers.

Device Description: Laser probes are an accessory used as part of a laser delivery system. They consist of a probe handpiece, strain relief, fiber optic cable, and connector. A laser light pipe may or may not be part of the probe. The probes must be connected to a laser console in order to deliver energy. The laser probe delivers the energy to the treatment site through an opening at the probe tip. Note, this submission is only in regard to the laser probe itself. It does not pertain to any other part of a laser delivery system such as the console.

Intended Use: Reprocessed laser probes are part of a laser delivery system and are used in ophthalmic procedures where laser energy is the mode of treatment.

Functional and Safety Testing: Representative samples of reprocessed laser probes underwent bench testing to demonstrate appropriate

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functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

SterilMed's reprocessed laser probes are substantially equivalent to HGM Inc.'s Fleischman-Swartz Endo-Ocular Probe (K840590), and to the counterpart devices from the original manufacturers. This conclusion is based upon the fact that these devices are essentially identical to the predicate device in terms of functional design, indications for use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Mr. Patrick Fleischhacker
Vice President Regulatory and Quality Control
SterilMed, Inc.
11400 73rd Avenue, North
Minneapolis, Minnesota 55369

Re: K012682
Trade Name: Reprocessed Laser Probe
Regulation Number: 886.4390
Regulation Name: Laser, ophthalmic
Regulatory Class: Class II
Product Code: GEX; HQF
Dated: August 10, 2001
Received: August 14, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Page

Device Name: Reprocessed Laser probes

Indications for Use:

These devices are reprocessed laser probes from various original equipment manufacturers (OEMs). Reprocessed laser probes are part of a laser delivery system and are used in ophthalmic procedures where laser energy is the mode of treatment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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