DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SterilMed, Inc.
% Dr. Bruce Lester
Vice President Research and Development
11400 73rd Avenue, North
Minneapolis, MN 55369

NOV 1 2004

Re: K012579 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: NKX
Dated: October 15, 2001
Received: October 22, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on November 8, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE

The following OEM models are covered under SVS for Phaco Tips (K012579):

ALCON

Small-Incision™ Phaco Tip
20 Gauge (0.9 mm)

5415S
5430S
5445S
5430H05
5430H20

Fluid-Dynamic™ Phaco Tip
19 Gauge (1.0 mm)

5115
5115F
5130
5130F
5145
5145F
6130
6130F
6145F

Turbosonics 20000 Legacy

20130M	8065740632
20130MM	8065740633
20130MV	8065740634
20130S	8065740635
20145	8065749847
20145MM	8065740848
20145MV	8065740849
20145S	8065740850
20130K	8065740887
20130KMM	8065740888
20130KMV	8065740889
20130KS	8065740890

ALLERGAN, INC.

AMO Titan™ Tips

OM342302E
OM342302A
OM342302B
OM342302C

OPTIKON

Standard U/S Tips

113201
113202
113203
113204
113205
113206
113207

Indications for Use

510(k) Number (if known): K012579

Device Name: Reprocessed Phaco Tip

Indications For Use:

The intended use of this device is to assist in the automated phacoemulsification of a natural crystalline lens.

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 Ear,
Nose and Throat Devises

510(k) Number K012579

K012579

NOV 0 8 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis, MN 55369
Ph: 763-488-3400
Fax: 763-488-3350

Date Prepared: August 7, 2001

Trade Name: Reprocessed Phaco Tips

Classification Name: and Number: Phacofragmentation Needle
Class II, 21 CFR 886.4670

Product Code: HQC

Predicate Device(s): The reprocessed phaco tip is substantially equivalent to: Alcon Limited Reuse Ultrasonic Tip (K981103), manufactured by Alcon; Phaco Tip (K914229), manufactured by Tri-Star Ophthalmic; Surgin High Efficiency Phaco Tip (K943102), manufactured by Surgin; and the counterpart devices from the original manufacturer.

Device Description: The phaco tip is a component of the phacoemulsification system. The tip is attached to an ultrasonic transducer. When properly stimulated, the transducer lengthens and shortens, causing the tip to oscillate at a specific frequency, usually between 27 to 64 kHz. Phacofragmentation of the cataractous lens is accomplished by the action of the phaco tip, a hollow needle located centrally in the device handpiece. When the device is used in the phacofragmentation mode both irrigation and aspiration occur simultaneously. The irrigating solution enters the eye via a collinear axial lumen, which encircles the phaco tip. The fragmentation process is the result of combined mechanical and ultrasonic action induced by the oscillating phaco tip. The cataractous lens and its fragments are disrupted by the phaco tip during the procedure and removed due to the pump suction at the phaco tip orifice. This submission is for the phaco tip only.

Intended Use:	The intended use of this device is to assist in the automated phacoemulsification of a natural crystalline lens.
Functional and Safety Testing:	Representative samples of phaco tips underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.
Conclusion:	The reprocessed phaco tips are substantially equivalent to the Alcon Limited Reuse Ultrasonic Tip (K981103), manufactured by Alcon; Phaco Tip (K914229), manufactured by Tri-Star Ophthalmic; Surgin High Efficiency Phaco Tip (K943102), manufactured by Surgin and the counterpart devices from the original manufacturer.

Table 1: Comparison of Subject Devices' and Predicate Devices' Characteristics

Device Characteristics	SterilMed's Reprocessed Phaco Tips	Alcon Limited Reuse Ultrasonic Tip (K981103)	Tri-Star Ophthalmic Phaco Tip (K914229)	Surgin High Efficiency (K943102)
Device Description	The phaco needle is the cylindrical, metal tip which is connected to the distal end of a phaco handpiece.	Same	Same	Same
Intended Use	The intended use of this device is to assist in the automated phacoemulsification of a natural crystalline lens.	Same	Same	Same
Principles of Operation	The needle is the component of a phaco system which, as driven by the ultrasonic handpiece, contacts and fragments the crystalline lens. Irrigation fluid flows between the external surface of the needle and the internal surface of an irrigation sleeve and into the eye. The emulsified lens material and irrigant are aspirated from the eye through the lumen of the phaco needle.	Same	Same	Same
Needle Tip Bevel Angle	0°-45° Round 30°-60°Oval 30° or 45° Kelman	15-45° Round 30° or 45° Oval	30° or 45° Round 30° or 45° Oval	15-45° Round 30° or 45° Oval
Shaft Shape	Straight or curved	Same	Same	Same
Outer Diameter	19-20 Gage	19-20 Gage	Unknown	19-20 Gage
Materials	Same*	Titanium alloy tip	Titanium alloy tip	Titanium alloy tip
Sterility	EtO SAL 10^{-6}	EtO Sterilization or Radiation Sterilization	Radiation Sterilization	Unknown
Product Code	HQC	Same	Same	Same

*Same materials as Alcon Phaco Tips, Tri-Star Phaco Tips, Surgin Phaco Tips or previously approved devices.