



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

MediSISS™, Inc.
c/o Ms. Brandi James
Regulatory Specialist
2747 SW 6th Street
Redmond, OR 97756

Re: K030179 – 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: 86 NKX
Dated: January 15, 2003
Received: January 17, 2003

Dear Ms. James:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on January 24, 2003. 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.

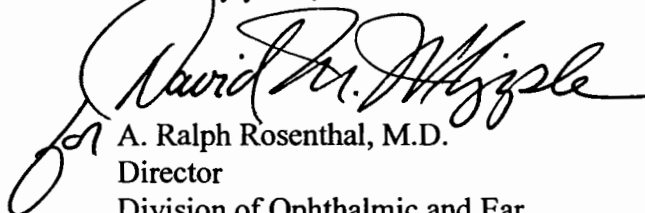
Page 2- Ms. Brandi James

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,



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 - Attachment 1 – List of Catalog Model Numbers

**ALCON Laboratories, Inc.'s
Series 20000™ Legacy® Phacoemulsification Tips
Catalog Model Numbers
To Be Reprocessed By MediSISS, Inc.**

30RTS	0.9mm, MicroTip™, Purple	30° Round
45RTS	0.9mm, MicroTip™, Purple	45° Round
30KTS	0.9mm, MicroTip™, Purple	30° Kelman®
45KTS	0.9mm, MicroTip™, Purple	45° Kelman®
8065790019	0.9mm, ABST™ MicroTip™, Purple	0° Round
8065790020	0.9mm, ABST™ MicroTip™, Purple	30° Round
8065790021	0.9mm, ABST™ MicroTip™, Purple	45° Round
8065790022	0.9mm, ABST™ MicroTip™, Purple	30° Kelman®
8065790023	0.9mm, ABST™ MicroTip™, Purple	45° Kelman®
8065740836	0.9mm, ABST™ MicroTip™, Purple	0° Round, Flared
8065740837	0.9mm, ABST™ MicroTip™, Purple	30° Round, Flared
8065740838	0.9mm, ABST™ MicroTip™, Purple	45° Round, Flared
8065740839	0.9mm, ABST™ MicroTip™, Purple	30° Kelman®, Flared
8065740840	0.9mm, ABST™ MicroTip™, Purple	45° Kelman®, Flared
15RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	15° Round
30RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	30° Round
45RT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	45° Round
30KT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	30° Kelman®
45KT	1.1mm, TurboSONICS® Standard U/S Tip, Blue	45° Kelman®
8065740791	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	0° Round
8065740792	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	30° Round
8065740793	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	45° Round
8065740794	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	30° Kelman®
8065740795	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	45° Kelman®
8065740805	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	0° Round, Flared
8065740806	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	30° Round, Flared
8065740807	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	45° Round, Flared
8065740808	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	30° Kelman®, Flared
8065740809	1.1mm, TurboSONICS® Standard ABST™ Tip, Blue	45° Kelman®, Flared

Indications for Use

Page 1 of 1

510(k) Number (if known): K030179

Device Name: MediSISS™ Reprocessed Phacoemulsification Tips/Needles

Indications for Use:

The MediSISS™ Reprocessed Phacoemulsification Tips/Needles are intended to emulsify and excise cataract tissue in ophthalmic microsurgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Frederick Beer
(Division Sign-Off)

(Optional Format 1-2-96)

**Summary of Safety and Effectiveness
for the
Reprocessed**

submitted by

JAN 24 2003

MediSISS, Inc.
P.O. 2060
723 Curtis Court
Sisters, OR 97759
Phone: (800)-860-9482
Fax: (541) 549-4527
Email: mabarker@medisissinc.com

Contact Person: Mary Ann Barker
Device Trade Names: MediSISS™ Reprocessed Phacoemulsification Tips/Needles
Common Names: Reprocessed Phacoemulsification Tips/Needles
Classification Names: Ophthalmic Devices, Phacofragmentation Needle, Electric, per 21 CFR §886.4670; Product Code: HQC; Regulatory Class: II

Identification of a Legally Marketed Predicate Device

The MediSISS™ Reprocessed Phacoemulsification Tips/Needles are substantially equivalent to the Phacoemulsification Tips/Needles as listed below:

Company

510(k) #

Alcon	K981103, K861380, K832836, K902798, K911808, K980292
-------	---

They are also similar to the reprocessed hot biopsy forceps reprocessed by Alliance Corporation and legally marketed and distributed pursuant to *Reprocessed Phacoemulsification Tips* 510(k) K012637. Likewise, SterilMed, Inc. *Reprocessed Phaco Tips*: - 510(k) K012579; and Vanguard Medical Concepts, Inc *Vanguard Reprocessed Phacoemulsification Needles/Tips*, 510(k) K0126098

Device Description

Reprocessed Phacoemulsification Tips/Needles are specifically designed to be used to emulcataractous lens material and remove it from the eye (phacoemulsification). Electric energy is generated in the Phacoemulsification System, delivered in a headpiece, and is finally converted to ultrasonic energy delivered through a hollow titanium needle or tip.

Irrigation fluid is delivered to the eye via a combination of an irrigation sleeve over the handpiece tip. The emulsified lens material is aspirated out of the eye through the center of the handpiece /tip assembly. The handpieces are routinely used repeatedly in multiple surgical procedures, while the tips are marketed as single use only. However, devices that the OEM has listed as predicates on their 510(k) i.e.: K981103, are reusable. Also, according to Alcons 510(k) K981103, the OEM took a single-use device and resubmitted it to clear for multiple reprocessing (usage up to 20 surgical procedures). This 510(k) was cleared to market on 6/23/98.

Intended Use

The MediSISS™ Reprocessed Phacoemulsification Tips are designed to emulsify and excise cataract tissue in ophthalmic microsurgical procedures.

Summary of Technological Characteristics

The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed devices(s) and the predicate device(s) have the same materials and product design. There are no changes to the claims, intended use, clinical applications, patient populations, performance specifications, or methods of operation. The technological characteristics of the reprocessed phacoemulsification tips/needles are the same as those of the legally marketed predicate devices. The technological characteristics of the reprocessed phacoemulsification tips/needles are the same as those of the legally marketed predicate devices. In addition the MediSISS™ manufacturing process includes 100 % visual and mechanical testing of all products prior to packaging, labeling, and sterilization.

Summary of Performance Data

The MediSISS™ Reprocessed Phacoemulsification Tips/Needles comply with the following standards, practices, and guidance's:

Sterilization Validation and EO Residuals:

- ANSI/AAMI/ISO 11135-1994, *Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization*
- ANSI/AAMI/ISO 10993-7:1995, *Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residual.*

Cleaning Validation:

- AAMI RDS0TIR No. 12-1994. *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for Device Manufacturers.* Association for the Advancement of Medical Instrumentation, Arlington, VA. Food and Drug Administration. 1996.

-
- *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, Office of Device Evaluation. FDA, Washington, D.C.*

Cleaning, sterilization, packaging validations, and visual/mechanical testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

MediSISS™ Reprocessed Phacoemulsification Tips/Needles undergo mechanical testing to demonstrate that the parts do not change in function. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging.

Conclusion

Since the MediSISS™ Reprocessed Phacoemulsification Tips/Needles meet the requirements of the stated standards and embody technological characteristics identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The MediSISS™ Reprocessed Phacoemulsification Tips/Needles will be reprocessed per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

In Accordance with the Federal Food, Drug, and cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, MediSISS™ concludes that the device(s)(Reprocessed Phacoemulsification Tips/Needles) are safe, effective, and substantially equivalent to the predicate devices as described herein.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.