K060648

PART B: 510(k) SUMMARY

MAR 19 2007

Submitter:
Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:
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Regulatory Affairs Engineer
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Date of preparation: March 9, 2007

Name of device:
Trade/Proprietary Name: Reprocessed Phacoemulsification Tips (Mackool)
Classification Name: *Needle, Phacoemulsification, Reprocessed*

Predicate Device	510(k) Title	Manufacturer
K955789	ALCON SERIES 20000 LEGACY MACKOOL SYSTEM	Alcon Laboratories

Device description: Phacoemulsification Tips are used to emulsify and excise cataract tissue in ophthalmic microsurgical procedures. When connected to the ultrasonic handpiece of a phacoemulsification system and activated, the Phacoemulsification Tip vibrates at an ultrasonic frequency that emulsifies cataract tissue. The extracted tissue is then aspirated away through the hollow tip. Irrigation of the eye with a saline solution compensates for the loss of volume in the eye when the cataract tissue is removed.

Intended use: Reprocessed Phacoemulsification Tips are intended to emulsify and excise cataract tissues in ophthalmic microsurgical procedures.

Indications statement: Reprocessed Phacoemulsification Tips are indicated for use to emulsify and excise cataract tissues in patients requiring eye surgery.

Technological characteristics: The design, materials, and intended use of Reprocessed Phacoemulsification Tips are identical to the predicate devices. The mechanism of action of Reprocessed Phacoemulsification Tips is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Alliance Medical Corporation's reprocessing of Phacoemulsification Tips includes removal of adherent visible soil and decontamination. Each individual Phacoemulsification Tip is tested for appropriate function of its

components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Phacoemulsification Tips. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Phacoemulsification Tips perform as originally intended.

Conclusion: Alliance Medical Corporation concludes that the modified devices (Reprocessed Phacoemulsification Tips) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Ascent Healthcare Solutions
c/o Ms. Katie Bray
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, AZ 85044

Re: K060648
Trade/Device Name: Ascent Reprocessed Phacoemulsification Tips
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: NKX
Dated: March 9, 2007
Received: March 12, 2007

Dear Ms. Bray:

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.

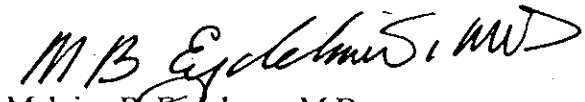
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 (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

2. Indications For Use Statement

510(k) Number (if known):

Device Name: Reprocessed Phacoemulsification Tips

Indications For Use: Reprocessed Phacoemulsification Tips are indicated for use to emulsify and excise cataract tissues in patients requiring eye surgery.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

MRB Nicholas

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

510(k) Number K060648