JUN 6 - 2005

K043358

ALLIANCE
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SECTION B: 510(k) SUMMARY

Submitter: Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Elizabeth Renken
Regulatory Affairs Specialist
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Date of preparation: November 15, 2004

Name of device: *Trade/Proprietary Name:* Reprocessed Ultrasonic Scalpels
Common or Usual Name: Reprocessed Ultrasonic Scalpels
Classification Name: Ultrasonic Surgical Instruments

Predicate device(s):

K980099, K993054 Ethicon Endo-Surgery (Ultracision)

Device description: Reprocessed Ultrasonic Scalpels are hand-held instruments designed to be used as part of an ultrasonic surgical system. These devices cut and coagulate tissue when attached to the ultrasonic hand piece and electrosurgical generator.

Intended use: Reprocessed Ultrasonic Scalpels are intended for use in soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, abdominal, pediatric, gynecologic and other open and endoscopic procedures.

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 device(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 population, performance specifications, or method of operation. The technological characteristics of the Reprocessed Ultrasonic Scalpels are the same as those of the legally marketed predicate device(s). In addition, Alliance Medical Corporation's reprocessing of Ultrasonic Scalpels includes

removal of adherent visible soil and decontamination. All devices are visually inspected and functionally tested prior to packaging, labeling, and sterilization operations.

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

- Biocompatibility
- Reprocessing Validation
- Sterilization Validation
- Function Tests

Performance testing demonstrates that Reprocessed Ultrasonic Scalpels perform as originally intended.

Conclusion: Alliance Medical Corporation concludes that the modified devices (Reprocessed Ultrasonic Scalpels) 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

JUN 6 - 2005

Ms. Elizabeth Renken
Regulatory Affairs Specialist
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K043358
Trade/Device Name: Alliance Medical Corporation Reprocessed Ultrasonic Scalpels (see attached list)
Regulatory Class: Unclassified
Product Code: NLQ
Dated: March 17, 2005
Received: March 18, 2005

Dear Ms. Renken:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The following Ultrasonic Scalpels are reprocessed by Alliance Medical Corp. K043398

Manufacturer	**Description**	**Model**
Ethicon Endo-Surgery	Long 5 mm Curved Shears	LCS-C5L
Ethicon Endo-Surgery	5 mm Curved Active Blade	LCS-C5
Ethicon Endo-Surgery	5 mm Curved Active Blade	LCS-C1
Ethicon Endo-Surgery	5 mm Knife Down Active Blade	LCS-K5
Ethicon Endo-Surgery	5 mm Blunt Active Blade	LCS-B5

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2. Indications for Use Statement

510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Ultrasonic Scalpels

Indications for Use: Reprocessed Ultrasonic Scalpels are indicated in general and endoscopic surgery to cut and coagulate soft tissue when hemostasis is desired with a minimal risk of burns.

Prescription Use X (per 21 CFR 801.109) or Over-the-Counter Use ____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K043358