JUN 29 2005

K051554 p/2

# PART B: 510(k) SUMMARY

**Submitter:**

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

**Contact:**

Moira Barton
Regulatory Affairs Manager
(480) 763-5300 (o)
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mbarton@alliance-medical.com

**Date of preparation:** June 11, 2003

**Name of device:**

*Trade/Proprietary Name:* Reprocessed External Fixation Devices
*Common or Usual Name:* External Fixation Devices, Fixation Appliance, Single/Multiple Component
Classification Name: *Single/Multiple Component Metallic Bone Fixation Appliances and Accessories and Smooth or Threaded Metallic Bone Fixation Fastener*

**Predicate device(s):**

**K012634** Reprocessed Smith & Nephew® External Fixation Devices

**Device description:**

External fixation devices are specially designed frames, clamps, rods, rod-to-rod couplings, pins, posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars and screws used for the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Materials used include metal alloys, plastic and composites. These materials are chosen to address a wide range of fractures and applications as well as to allow for the appropriate amount of rigidity and stability.

**Intended use:**

External Fixation Devices are intended to be used for the fixation of supracondylar, or condylar fractures of the femur; for fusion of a joint; for surgical procedures that involve cutting the bone, for fixation of bone fractures; bone reconstruction; as a guide pin for insertion of other implants; or may be implanted through the skin so that a pulling force or traction may be applied to the skeletal system; and others may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

K051554 p2/2

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| **Indications statement:** | Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects. |
| **Technological characteristics:** | The design, materials, and intended use of the Reprocessed External Fixation Devices are identical to the predicate devices. The mechanism of action of the Reprocessed External Fixation Device is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. The only change is the modified external fixation devices will be provided non-sterile. Sterilization of the devices will occur in the hospital prior to use. |
| **Performance data:** | Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed External Fixation Devices.<br>• Validation of reprocessing<br>• Function Testing<br>Performance testing demonstrates that Reprocessed External Fixation Devices perform as originally intended. |
| **Conclusion:** | Alliance Medical Corporation concludes that the modified device (the Reprocessed External Fixation Device) is 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 29 2005

Ms. Moira Barton
Regulatory Affairs Manager
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K051554
Trade/Device Name: Alliance Medical Corporation Reprocessed External Fixation Devices
Regulation Numbers: 21 CFR 888.3030; 21 CFR 888.3040
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories; Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: KTT, KTW, JEC
Dated: June 6, 2005
Received: June 13, 2005

Dear Ms. Barton:

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.

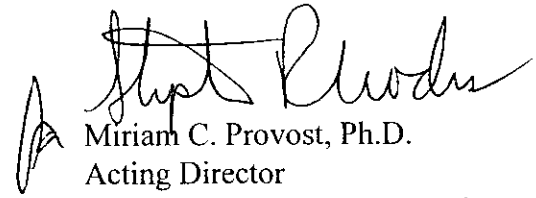
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# II. Indications for Use Statement

K051554

**Device Name**: Alliance Medical Corporation Reprocessed External Fixation Devices

**Indications for Use**: Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051554