

1023714

510(k) SUMMARY

FEB 03 2003

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

Contact: Don Selvey
Vice President, Regulatory Affairs & Quality Assurance
(480) 763-5300 (o)
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Date of preparation: August 29, 2002

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): Legally marketed external fixation devices under various 510(k) premarket notifications.

K802814 Orthofix® Axial External Fixation System
K831576 Orthofix®
K944092 Additional Accessories for the Orthofix® System
K955848 Orthofix® Modulsystem

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.

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.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed External Fixation Devices.

- Validation of reprocessing
- Function Testing

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Selvey
Vice President Regulatory Affairs and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

FEB 03 2003

Re: K023714
Trade Name: Reprocessed External Fixation Devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, KTW, JEC
Dated: November 1, 2002
Received: November 5, 2002

Dear Mr. Selvey:

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.

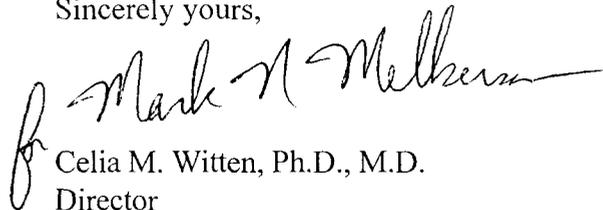
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Don Selvey

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 (301) 594-4659. 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 handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

510(k) Number (if known): K023714

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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milburn

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

510(k) Number K023714

Prescription Use _____
(per 21 CFR 801.109)

or

Over-the-Counter Use _____