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ALLIANCE
MEDICAL CORPORATION

SECTION B: 510(k) SUMMARY

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Submitter: Alliance Medical Corporation
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Contact: Jenn Selvey
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Date of preparation: November 16, 2004

Name of device: *Trade/Proprietary Name:* Reprocessed EP Technologies Electrophysiology Catheters
Common or Usual Name: Electrophysiology Catheter or Electrode Recording Catheter
Classification Name: Electrode Recording Catheter

Predicate device:

K924109	Steerocath Dx
K924163	Polaris LE
K003452	Polaris X
K954651	Electrode Recording Catheter
K012708	Reprocessed Electrophysiology Catheters

Device description: Diagnostic electrophysiology (EP) catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a hand piece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tip of deflectable catheters can be deflected into a curve by manipulating the hand piece.

Intended use: Reprocessed Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures.

Indications statement: Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures.

Technological characteristics: The design, materials, and intended use of Reprocessed Electrophysiology Catheters are identical to the predicate devices. The mechanism of action of Reprocessed

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Electrophysiology Catheters 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.

Alliance Medical Corporation's reprocessing of EP Technologies Electrophysiology catheters includes removal of adherent visible soil and decontamination. Each individual electrophysiology catheter 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 the Reprocessed Electrophysiology (EP) Catheters.

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

Performance testing demonstrates that Reprocessed Electrophysiology (EP) Catheters perform as originally intended.

Conclusion: Alliance Medical Corporation concludes that the modified device (the Reprocessed Electrophysiology Catheter) 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

MAR 2 3 2005

Alliance Medical Corporation
c/o Ms. Jenn Selvey
Research and Development Specialist
10232 South 51st Street
Phoenix, AZ 85044

Re: K043393
Trade Name: Reprocessed EP Technologies Electrophysiology Catheters (See Enclosed List)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: NLH
Dated: January 19, 2005
Received: January 21, 2005

Dear Ms. 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.
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/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Orig models found to be SE
EPT-Dx (5)
1101
1102
1103
1300
1301
Valve Mapper SteeroCath-Dx (7)
2200
2250
2270
2250K2
2270K2
2270L
2270N4
Polaris-Dx (15)
5571
5572
5574
5570S
5571S
5572S
5573S
5574S
5577
5579
5427S
9663S
5575
5576
5578
Polaris LE Mapping (2)
5593
5595

2. Indications for Use Statement

510(k) Number (if known): K043393

Device Name: Alliance Medical Corporation Reprocessed EP Technologies Electrophysiology (EP) Catheters

Indications for Use: Reprocessed diagnostic EP catheters are indicated for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043393