



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 1 2004

Alliance Medical Corporation  
c/o Ms. Moira Barton  
Regulatory Affairs Manager  
10232 South 51<sup>st</sup> Street  
Phoenix, AZ 85044

Re: K030187 - Supplemental Validation Submission  
Trade Name: See Enclosed List  
Regulation Number: 21 CFR 870.1220 & 870.2900  
Regulation Name: Electrode Recording Catheter and Patient Transducer and Electrode  
Cable (including connector)  
Regulatory Class: Class II (two)  
Product Code: NLH & DSA  
Dated: January 17, 2003  
Received: January 21, 2003

Dear Ms. Barton:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on September 24, 2003. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices 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,



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

Enclosures

Enclosure – List of Devices

<b>Bard (24)</b>
200131
200344
200526
200740
200769
200770
200794
200795
200796
200797
200798
201101
201102
201103
201104
201105
201106
201107
201109
201114
320001
320002
7FAM00004
7FAM00007



SEP 24 2003

K030187 P.1/2



ALLIANCE  
MEDICAL CORPORATION

## PART B: 510(k) SUMMARY

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**Contact:** Moira Barton  
Senior Regulatory Affairs Specialist  
(480) 763-5300 (o)  
(480) 763-5310 (f)

**Date of preparation:** 6/13/2002

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

**Predicate device(s):**

**K891908** Bard Tip Deflecting Electrode Catheter  
**K874208** Bard Octapolar Electrode Catheter  
**K881966** Electrophysiology Electrode Catheter with Silver/Silver  
**K992373** Orbiter ST Diagnostic Electrode Catheter

**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 handpiece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tips of deflectable catheters can be deflected into a curve by manipulating the handpiece; fixed curve catheters have an established distal tip shape.

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

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

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

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

**Conclusion:** Alliance Medical Corporation concludes that the modified device (the Reprocessed Electrophysiology (EP) Catheter) is safe, effective and substantially equivalent to the predicate devices as described herein.