NOV 2 3 2004

K041978

SECTION B: 510(k) SUMMARY

Submitter:

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

Contact:

Eric Varty
Research and Development Manager
(480) 763-5335 (o)
(480) 763-5320 (f)
evarty@alliance-medical.com

Date of preparation: July 15, 2004

Name of device:

Trade/Proprietary Name: Reprocessed Diamond Burs
Common or Usual Name: Diamond Burs
Classification Name: Dental Diamond Coated Bur, Dental Diamond Instrument, ENT diamond Coated bur

Predicate device:

K#	Device Description	Product Code
K901967	Dendia Werk Burs and Cutting Discs	DZP

Device description: Diamond Burs are specially designed surgical accessories designed to help the surgeon cut and drill bone and bony structures during orthopedic procedures.

Intended use: Diamond burs are intended for use to cut and drill bone and bony structures during orthopedic procedures.

Indications statement: Reprocessed diamond burs are indicated for use in patients requiring surgery involving bone and bony structures during orthopedic procedures.

Technological characteristics: The design, materials, and intended use of Reprocessed Diamond Burs are identical to the predicate devices. The mechanism of action of Reprocessed Diamond Burs 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 Diamond Burs includes removal of adherent visible soil and decontamination. Each individual Diamond Bur 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 Diamond Burs.

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

Performance testing demonstrates that Reprocessed Diamond Burs perform as originally intended.

Conclusion: Alliance Medical Corporation concludes that the modified device (the Reprocessed Diamond Bur) 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

NOV 23 2004

Mr. Eric Varty
Research and Development Manager
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Re: K041978
Trade/Device Name: Alliance Medical Corporation Reprocessed Diamond Burs
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: NLN
Dated: November 10, 2004
Received: November 12, 2004

Dear Mr. Varty:

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.

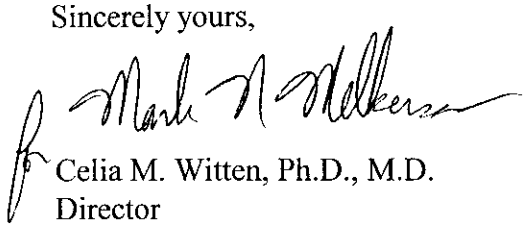
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.html

Sincerely yours,



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

2. Indications for Use Statement

510(k) Number (if known): K041978

Device Name: Alliance Medical Corporation Reprocessed Diamond Burs

Indications for Use: Reprocessed Diamond Burs are indicated for use in patients requiring surgery involving bone and bony structures.

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

510(k) Number K041978

Concurrence of CDRH, Office of Device Evaluation (ODE)

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