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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	The Anspach Effort 4500 Riverside Drive Palm Beach Gardens, FL 33410
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Date Prepared	September 5, 2008
Device Name	Cranial Perforator
Classification Name	Drills, Burrs, Trephines & Accessories (Compound Powered)
Device Classification	Class II Neurology Devices Panel 21 CFR § 882.4305
Predicate Devices	Anspach Access Cranial Perforator -> K982991 Codman & Shurtleff, Inc. Disposable Perforator -> K933894, K071931 and Disposable Perforators Jacobs, Hudson -> K791101 Acra Cut, Inc. Automatic Cranial Drill (Perforator) -> K892866 and Acra Cut, Inc. -> K833266
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The Cranial Perforator per CFR, Part 882.4305, is a bone

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cutting and drilling instrument used in conjunction with a surgical motor and speed reducer attachment to drill holes through a patient's skull. The Cranial Perforator employs a clutch mechanism to disengage drilling action upon initial penetration of the skull to prevent plunging of the perforator tip into the underlying dura and brain tissues. The device is a Class II (USA) device.

The Cranial Perforator is a device similar in design and construction to other devices currently on the market; (e.g.: Acra-Cut model DGR-1; 14/11mm).

The Cranial Perforator is a compound drill which requires a motor to provide speed (70 – 80K RPM) and torque. But a speed reducer attachment is necessary to limit motor speed while delivering necessary torque. For this application the recommended motors are the Anspach Black Max, MicroMax and eMax motor systems. For speed reduction, it is recommended only the Anspach Speed Reducer attachments be used. The speed range when used with the listed Anspach equipment is 800 to 1200 RPM.

Indications for Use

"The Cranial Perforator is a sterile, single use cutting device intended for performing cranial trephination in bone **at least 3 mm thick** (i.e., adult skulls).

Technological Characteristics

Substantial equivalence of the Cranial Perforator is based on:

1. Design features which are similar to the currently available Acra-Cut DGR-1.
2. Performance testing which demonstrates the declutch features of Anspach's Cranial Perforator is the same as the Acra-Cut DGR-1.

Performance Testing

The Anspach Cranial Perforator (75-0002-1) was tested for performance and safety; refer to Verification Report 06-0708, using a comparative method to predicate cranial perforators Acracut and Codman. This test were performed on human cadaver test samples and a pneumatic drill set at 120 psi, the maximum allowed, using a 60:1 gear ratio Hudson Style speed reducer. The Anspach Cranial Perforator was found to be equivalent to the competitors

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with respect to Plunge and Early Declutch failures. The Anspach Cranial Perforator was found to meet the user requirement of a cutting rate equal to or greater than 0.24 mm/sec. The Anspach Cranial Perforator was capable of creating clean holes when performing perforations. The Anspach Cranial Perforator did not exhibit any gross mechanical failures.

Conclusion

The Cranial Perforator is equivalent to the currently marketed Acra-Cut DGR-1 and Codman 26-1221 which provides similar functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Anspach Effort, Inc.
% Mr. Jim Banic
Senior Regulatory Affairs Specialist
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

DEC 22 2008

Re: K082637
Trade/Device Name: Cranial Perforator
Regulation Number: 21 CFR 882.4305
Regulation Name: Powered compound cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBF
Dated: November 20, 2008
Received: November 21, 2008

Dear Mr. Banic:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082637

Device Name: Cranial Perforator

Indications for Use:

"The Cranial Perforator is a sterile, single use cutting device intended for performing cranial trephination in bone **at least 3 mm thick** (i.e., adult skulls).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM 12/22/2008

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

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