APR 30 2008

510(k) Summary of Safety and Effectiveness

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

K080802

Submitter	The Anspach Effort, Inc. 4500 Riverside Drive Palm Beach Gardens, FL 33410
Official Correspondent	Jim Banic Senior Regulatory Affairs Specialist The Anspach Effort, Inc. 4500 Riverside Palm Beach Gardens, FL 33410 Tel. 561-627-1080 Fax. 561-625-9110 Email: jimb@anspach.com
Date Prepared	March 17, 2008
Device Name	eMax 2 Plus System
Classification Name	Motor, Drill, Electric
Device Classification	Class II Neurology 21 CFR § 882.4360
Predicate Devices	eMax Drill System-> K011444
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The eMax 2 Plus System is an electrically powered drill motor with a series of attachments designed for use on the bones of the cranium and spine. The system components include a control console, the motor hand piece and foot control switch. The control console supplies power to the motor through a detachable cable. This system is non-sterile.
Indications for Use	The eMax 2 Plus System is intended use is for Cutting and shaping bone including spine and cranium.

Technological Characteristics	The eMax 2 Plus System is made of the same materials and contains features and functions which are similar to the currently available eMax Drill System. The same cutters, attachments and accessories which interface with the eMax Drill System will interface with the eMax 2 Plus System.
Conclusion	The eMax 2 Plus System is substantially equivalent to the currently marketed eMax Drill System cleared by K011444 on August 8, 2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 2008

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

Re: K080802
Trade/Device Name: eMax 2 Plus System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: II
Product Code: HBC
Dated: March 17, 2008
Received: March 31, 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): K080802

Device Name: eMax 2 Plus System

Indications for Use:

The eMax 2 Plus System is intended for Cutting and shaping bone including spine and cranium.

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)

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

510(k) Number K080802