APR 1 5 2004

K040186

Exhibit 10

Section 17

510(k) SUMMARY

Anspach MRI Safe Surgical Drill System

The MRI Safe Surgical Drill System is a class II medical device that includes a pneumatic drill motor and foot control; a variety of nosepiece attachments; and bone dissection tools. To make the drill system "MRI Safe", ferrous metals comprising each system component have been replaced with materials known to have significantly lower or no magnetic susceptibility. However, when imaging is being performed the drill system must be moved to at least Zone 4.

The MRI Safe Drill System foot control is not intended to be placed within the sterile field nor within MRI magnetic field (Zones 1-3). The MRI Safe motor does not require continuous oiling and runs at slower speed (60-65k RPM) than non-MRI safe motors (80-85k RPM). Nosepiece attachments support the cutter to minimize vibration, wobble and whipping. They are a direct contact (with patient) device and are distributed clean, non-sterile for reusable applications. MRI cutters are identical to Anspach non-MRI safe cutters with exception of materials and indications for use. Cutters are surgically invasive, direct contact (with patient) devices and are distributed pre-sterilized to SAL 10^{-6}. MRI cutters carry additional warnings to advise user that "dulling" may occur faster than non-MRI safe cutters if overused or reused.

There are no known unacceptable risks/hazards associated with use of the MRI drill system, when used as indicated. Additional risks identified (over non-MRI cutters) and addressed through design and/or labeling include: 1) Loss or reduction in surgeon control of the motor during surgical use; 2) Adverse effects of magnetic fields on motor operation (speed/torque, heat generation (over-heating), noise, etc.); 3) Drill, foot control, attachment or cutter becoming a projectile during use or while otherwise in the MRI environment; 4) MRI image distortion; 5) Reduced life expectancy of cutters; and 6) Unintended use of non-MRI safe system components with the MRI safe system.

MRI Safe system (including motor, foot control, nosepiece attachments and cutters), is indicated for intra-operative (non-imaging) use within a MRI system rated at 0.5 Tesla or less, for surgical cutting, shaping and removal of bone, including bones of the skull and spine. The MRI Safe Surgical Drill System (including drill motor and foot control, nosepiece attachments and cutters), is contraindicated for presence within zones 1-3 of a MRI system while imaging is actually being accomplished. Presence of the equipment in Zones 1-3 during imaging could cause unacceptable image distortion.

Cleaning, sterilization and storage conditions are specified on product package inserts and product labeling complies with U.S, European Union and in other global market requirements.

The MRI safe drill system is substantially equivalent in form, design to other Anspach pneumatic drill systems including MicroMax and the original 65K, their nosepiece attachments and cutters. Principle design differences are in materials, indications for use and a slightly modified locking mechanism, that prevents interchangeability between MRI safe and non-MRI safe system components.

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2004

Mr. William G. Conety
Director, Regulatory Affairs
and Quality Assurance
Anspach Companies
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K040186
Trade/Device Name: MRI Safe Surgical Drill System
Regulation Number: 21 CFR 883.4370; 21 CFR 882.4310
Regulation Name: Pneumatic drill, Powered simple cranial drills, burrs, trephines and their accessories
Regulatory Class: II
Product Code: HBB, HBE
Dated: January 23, 2004
Received: January 28, 2004

Dear Mr. Conety:

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 (301) 594-4659. 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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): K040186

Device Name: "MRI Safe Surgical Drill System"

Indications For Use:

The MRI Safe Surgical Drill System (including pneumatic drill motor, foot control, nosepiece attachments and cutters), is indicated for intra-operative (non-imaging) use within a Magnetic Resonance Imaging (MRI) environment rated at 0.5 Tesla or less, for surgical cutting, shaping and removal of bone, including bones of the skull and spine.

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K640186