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MAR 15 2004

[redacted]

510(k) SUMMARY: – Advanced Micro Saw Attachments

CLASSIFICATION : US Class II

PERFORMANCE STANDARDS:

No known performance standards.

DESIGN, MATERIALS AND OPERATION CHARACTERISTICS:

Keyless driver connects to surgical motor (or eMax Console – electric driver) and holds the micro saw head.. It reduces motor speed and drives the attached saw blade.

There designs: Black Max, MicroMax/eMax and "stand alone" electric driver certified to:

- UL 2901-1: Second Addition, Rev. 10/24/97
- CSA-C22.2 No. 601.1- M90, including General Instruction No. 1
- EN60601-1, Issue 2, (including A1, A2, A11-13)

Drivers are non-invasive and non-patient contact; contain no materials or substances which could be transferred to patient. Drivers cannot internally transfer materials or substances from motor. Drivers are reusable and can be cleaned with soap/water or isopropyl alcohol and can withstand temperatures of up to 278°(F) for up to 30 min. (static).

Micro saw head attaches to keyless driver without tools. Head converts motor rotational drive to sagittal, oscillating or reciprocating motions. Heads may be surgically invasive. Unintentional contact may occur due to proximity of blade and tissues of surgical site. Heads are constructed of biocompatible materials and contain no substances which could be transferred to patient. Like drivers, heads cannot internally transfer substances from motor. Heads are reusable and can be cleaned with soap-water or isopropyl alcohol and can withstand temperatures up to 278°(F) for up to 30 min. (static).

Saw blades are pre-sterilized, single-use, disposable bone cutting blades. Saw blades are sterilized to an appropriate SAL as specified by recognized standards for sterilization.

RISK ASSESSMENT:

Risk assessment has been accomplished for the micro saws. All identified risks and hazards associated with use of the micro saws were capable of being reduced to acceptable levels through design, process and/or labeling activities.

INDICATIONS / CONTRAINDICATIONS:

There are no specific indications or contraindications for use of micro saw attachments. Generally, micro saw attachments are indicated for use only by qualified and trained surgeons, with Anspach surgical drill motor systems, for surgical cutting, shaping and removal of bone, including bones of the spine and cranium.

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CLEANING/STERILIZATION/MAINTENANCE

Cleaning, sterilization and maintenance instructions are provided in product use manuals available to all purchasers and Instructions (directions) For Use (IFU/DFU) that accompany each product. Unauthorized repairs and maintenance can be grounds for termination of warranty benefits.

WARNINGS and CAUTIONS:

Generic Warnings for use of Anspach products are specified in manuals and on product inserts. For safe and effective use of any Anspach product, specialized training is required as surgical techniques are highly specialized procedures. Improper surgical technique or improper use of product can cause injury or death to a user or patient and damage to product.

SUBSTANTIAL EQUIVALENCE:

Advanced micro saw attachments are substantially equivalent to Anspach Micro Saws.

	OLD Micro Saw			**NEW** Micro Saw		
	Sagittal	Reciprocating	Oscillating	Sagittal	Reciprocating	Oscillating
Use w/Electric motor	Y	Y	Y	Y	Y	Y
Use w/Pneumatic motor	N	N	N	Y	Y	Y
Stand alone keyless driver	N	N	N	Y	Y	Y
Tool-less attachment	Y	Y	Y	Y	Y	Y
90° degree head	N	N	Y	N	N	Y
180° degree head	Y	N	N	Y	N	H
20° angled head	N	N	N	Y	N	N
Shaft diameter						
Speed reduction*						
Maximum speed						
Degree of ark			[PROPRIETARY INFORMATION]			
Stroke length						
Operating temp.(Max)						
Stainless steel construction	Y	Y	Y	Y	Y	Y
Corrosion resistant bearings	N	N	N	Y	Y	Y
Immersion cleaning**	N	N	N	Y	Y	Y
4 Min flash sterilization**	N	N	N	Y	Y	Y
Pre-sterilized blades (SAL)	Y	Y	Y	Y	Y	Y

* OLD: Speed reduction achieved only by power reduction. NEW: Speed reduction achieved with internal gear reduction mechanism.

** Excluding saw blades which are single use and disposable.

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2004

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

Re: K040076
Trade/Device Name: Advanced Micro Saw Attachments –
Sagittal, Oscillating and Reciprocating
Regulation Number: 21 CFR 882.4310, 21 CFR 882.4360
Regulation Name: Powered simple cranial drills, burrs, trephines and their accessories;
Electric cranial drill motor
Regulatory Class: II
Product Code: HBE, HBC
Dated: January 12, 2004
Received: January 16, 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

510(k) Number: K040076

Device Name: Advanced Micro Saw Attachments - Sagittal, Oscillating and Reciprocating

INDICATIONS FOR USE:

Anspach micro saw attachments are indicated for use with eMax electrical and Black Max, MicroMax pneumatic drill systems for surgical cutting, shaping and removal of bone, including bones of the spine and cranium.

DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040076

Prescription Use: ✓ OR Over-the-Counter Use: _____ Per 21 CFR 801.109)