DEC 17 2004

510(k) SUMMARY: – **Specialty Attachment**
Minimal Access Spinal Attachment system

CLASSIFICATION: US Class II K04 2783

PERFORMANCE STANDARDS:

No known performance standards.

DESIGN, MATERIALS AND OPERATION CHARACTERISTICS:

The Minimal Access Spinal Attachment system consists of three basic components: Angled Motor Adaptor (20° Driver Body); Nose-tube/bearing housings; and a variety of bone dissection tools (cutters").

Angled Motor Adaptor (20° Driver Body): Two designs; one for the Black Max motor and one for MicroMax/XMax and eMax Motors.

The 20° Driver Body is a non-invasive and non-patient contact component of the Minimal Access Spinal Attachment system that connects to the surgical motor. Unlike other attachments, the Minimal Access Spinal Attachment is designed to provide a 3.0mm length adjustment of the nose-tube/bearing sleeves.

The 20° Driver Body is reusable, distributed clean and nonsterile. It is designed to be cleaned with (non-immersion) soapy-water and/or full immersion in Isopropyl alcohol. Recommended cleaning and sterilization processes are provided with each device.

Nose tube/bearing sleeves: Four initial tube designs*

1) Long Curved (10+/- 2°)
2) Long Straight
3) Short Curved (10+/- 2°)
4) Short Straight

* Additional lengths to become available

The nose-tube/bearing sleeve is reusable, provided it is properly handled, cleaned, and maintained as directed by directions for use (DFU), provided with each product. When increased bearing wear is observed (increased heat and/or noise), the bearing tube is removed from the Driver Body and discarded. A replacement nose-tube is then simply inserted and locked onto the Driver. Like the 20° Driver, nose-tube/bearing sleeves can be steam autoclaved before use in accordance with DFU.

Cutters (Bone Dissection Tools):

Minimal Access Spinal Attachment system cutters are the variety of pre-sterilized, single-use, disposable bone dissection tools. Minimal Access Spinal Attachment cutters are individually packaged and distributed pre-sterilized. A variety of cutting tip designs and diameters in

lengths to fit all Nose tube/bearing housings are available with additional sizes and head configurations available in the future.

Cutters are of the same basic design and materials as other currently distributed cutters and are individual packaged and pre-sterilized. Terminal sterilization is achieved by Irradiation to a sterility assurance level (SAL) of 10^{-6}. User assembly instructions are provided with each component of the system and also in a variety of catalogs and surgical manuals.

RISK ASSESSMENT:

Risk assessment has been accomplished for the Minimal Access Spinal Attachment system. All identified risks and hazards associated with design, production, performance and use of the Minimal Access Spinal Attachment system were capable of being reduced to acceptable levels through design, process and/or labeling activities.

INDICATIONS / CONTRAINDICATIONS:

The Anspach Minimal Access Spinal Attachment system is indicated for use as a nosepiece attachment with Anspach pneumatic and electric surgical drill systems for surgical cutting, shaping and removal of bones, including bones of the spine and cranium.

Anspach manufactured equipment is contraindicated for surgical use by anyone not qualified through education and experience, in proper use of Anspach product.

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:

The Minimal Access Spinal Attachment system is substantially equivalent to the Anspach Angled Micro-nose Attachment and the Medtronic (Midas Rex) "Micro-Telescoping System". See attached comparison chart on the following page:

	Anspach Minimal Access	Anspach MICRO/MDA	Midas* Rex
Use w/Electric motor[1]	Y	Y	Y
Use w/Pneumatic motor[1]	Y	Y	Y
Tool-Less attachment	Y	Y	Y
20° angled driver	Y	Y	N
Length adjustable	Y	N	Y
Nose tube diameters	4-5mm (taper)	3-4mm	5.0mm
Nose tube lengths	7-30cm	16cm	8-15cm
Curved nose tube radius	10+/- 2°	N	10° [2]
Cutter shaft diameter	1.4mm	1.43mm	1.4mm[2]
Operating temperature(Max)	120°	120°	120°[2]
Stainless steel construction	Y	Y	Y
Corrosion resistant bearings	Y	Y	?
Immersion cleaning	Y[3]	N	N
4 Min flash sterilization**	Y	Y	Y
Sterrad sterilization	Y	Y	?
Pre-sterilized cutters (SAL10[6])	Y	Y	Y
Service/Repair (20° Driver)	Y	Y	?[2]
Service/Repair (Nose-tubes)	N[4]	Y	?[2]
Service/Repair (Cutters)	N	N	?[2]

* Medtronic, Midas Rex "*Legend*"™ Micro-Telescoping System

**Flash sterilization is only recommended for immediate use in the operating theater.

[1] Anspach product compatible with Anspach product only.

[2] Information provided should be considered average or unknown (?), as it is unknown what level of design, production or performance controls are established for specific devices.

[3] Nose tubes may be fully immersed. 20° Driver is designed for full immersion in Isopropyl alcohol during cleaning processes for sterilization and reuse, but continues to be labeled "Do not Immerse" to prevent immersion in saline or other fluids while in the surgical theater.

[4] Nose-tubes are designed for reuse until bearing wear (heat/noise) becomes noticeable, at which time nose-tubes should be disposed of.

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

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

Re: K042783
Trade/Device Name: Minimal Access Spinal Attachment System
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBE
Dated: December 8, 2004
Received: December 10, 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 (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,

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: K042783

Page 1 of 1

Device Name: Minimal Access Spinal Attachment system

INDICATIONS FOR USE:

The Anspach Minimal Access Spinal Attachment system is indicated for use as a nosepiece attachment with Anspach pneumatic and electric surgical drill systems for surgical cutting, shaping and removal of bones, including bones of the spine and cranium.

Prescription Use: X 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 K042783