Exhibit 07: 510(k) SUMMARY: – Anspach Powered Kerrison System (PKS)

BACKGROUND:

Spine surgeons gain access to the posterior aspect of the spinal cord and its nerve roots by removing a portion of the vertebra called the lamina (laminectomy). The procedure is typically performed by using a manual "Kerrison" rongeur, powered rongeur or by some highly skilled surgeons using a high-speed drill (HSD) system with a long-straight or craniotome nosepiece attachment and burr (Anspach or similar). Powered, manual rongeurs and craniotome attachments have a footplate that is inserted between the bone of the lamina and the underlying nerve. The footplate helps to guide the blade and helps protect surrounding tissues. Once the footplate is under the bone, the surgeon squeezes the handle of the rongeur which advances the instrument's blade, bringing the cutting surface down to the footplate, biting off a small piece of the lamina.

DESIGN, MATERIALS AND OPERATION CHARACTERISTICS:

Design: The Anspach PKS is designed to be operated by either pneumatic or electric power but without the forceful, rapid forward stroke of a stationary blade in other powered rongeur systems. The Anspach PKS removes bone using a high speed rotational (85k max. rpm) cutting blade advanced by an operator controlled trigger mechanism.

PKS consists of four basic component parts:

- Pistol Grip Trigger Assembly housing
- Straight Nose-Tube Attachment
- Shielded Attachments
- Cutters

Materials: PKS is constructed of the same materials that are used in construction of other Anspach motors, nosepiece attachments and cutters. There are no new or unusual materials used in construction of any of the system's component parts. System components that contact human tissues are constructed of materials recognized as safe for their intended uses, contact and duration.

Operation Characteristics: Surgeon simply removes the previous cutting burr and attachment being used and reassembles the motor with PKS in a quick, simple four-step process

01 Select and attach desired PKS straight nose-tube attachment to motor.
02 Insert through straight nose-tube attachment and lock the desired cutter.
03 Insert motor/nose-tube/cutter assembly through trigger housing assembly and lock into place.
04 Insert nose-tube/cutter assembly through burr-guard attachment and locked onto trigger assembly housing.

PKS is now assembled and ready to use. **Note**: Cutter tip is not extended and is in its retracted position inside straight nose-tube attachment. Surgeon places footplate of PKS burr guard between lamina and nerve (or other soft tissue or structure) and by gripping pistol-grip handle firmly, lightly squeezing the trigger to advance high-speed burr to the bone, which is quickly and effectively cut away. Releasing the trigger causes the high-speed burr to be retracted back into the straight nose-tube attachment, which can then be repositioned and the procedure repeated.

INDICATIONS / CONTRAINDICATIONS:

Anspach PKS is indicated for cutting and shaping bone, including bones of the skull and spine. There are currently no, known specific contraindications with use of the device.

CLEANING/STERILIZATION/MAINTENANCE:

PKS cutters are single-use, disposable and cleaning, reprocessing and re-use are not recommended. Anspach cannot guarantee maximum cutter effectiveness after its use and/or 3rd party re-processors. To ensure maximum bone cutting performance, use of a new, previously unused cutter is strongly recommended for each patient/procedure.

The PKS Pistol-Grip Handle and straight nosepiece attachments are not designed to be immersed into any liquids during cleaning (Damage to high-speed bearings could result). Manual cleaning with mild soap and water is recommended with internal cleaning accomplished by an accessory cleaning brush (available from Anspach).

Sterilization of PKS is the same as with other Anspach motor and attachment system due to the similarity in materials, design complexity and materials. Recommended Sterilization is by Steam Autoclave at the following processing parameters: **NOTE**: Complete cleaning, sterilization and storage conditions are specified on product package inserts available with every PKS component and within a variety of surgical equipment manuals.

Steam Autoclave/Gravity Air Displacement	270+/- 2° (F) [132 +/-1°(C)] for 20 minutes unwrapped
Steam Autoclave/High Speed vacuum	270+/- 2° (F) [132 +/-1°(C)] for 10 minutes wrapped or 8 minutes unwrapped

WARNINGS:

Generic Warnings for use of Anspach Motor Systems, Attachments and Cutters are specified on product inserts and equipment manuals.

For safe and effective use of any Anspach product, it is strongly suggested that specialized training be undertaken since surgical techniques using Anspach products are highly specialized and complex procedures. Improper surgical technique or improper use of Anspach products can cause severe injury or death to a user or patient and cause severe damage to Anspach products and/or other manufacturer's or user facility's equipment.

CAUTIONS:

Generic cautions for use of Anspach Motor Systems, Attachments and Cutters are specified on product inserts and equipment manuals (See Section 14 and associated exhibits).

SUBSTANTIAL EQUIVALENCE:

The Anspach PKS is a rongeur, powered by a pneumatic (air/gas) or an electric motor currently manufactured and distributed by Anspach (K831756 - Black Max; K965080 - MicroMax and; K011444 - eMax). Anspach PKS is similar in appearance, materials and has the same intended uses as other powered rongeurs and the same intended uses as both powered and manual rongeurs. The

foot-piece of the PKS shielded attachment is identical in materials and design to the foot-piece of other Anspach shielded attachments (K974025).

Principle difference between Anspach PKS and other rongeurs is that PKS uses a high-speed motor driven rotating burr to dissect bone instead of the straight, rigid blade system of other rongeurs. Difference between Anspach PKS and surgical techniques employing high-speed drill (HSD) systems is that PKS provides a long attachment (greater surgeon visibility) with an integral shielding feature identical to other Anspach Shielded Attachments.

	Principle Differences Between Predicate Devices/Methods and Anspach PKS	Powered Rongeur	Manual Rongeur	HSD System	Anspach PKS
01	**US Classification**	II	I	II	II
02	**EU Classification**	IIa	I (?)	IIa	IIa
03	**Manually Powered**	No	Yes	No	Yes
04	**Externally powered**				
	Gas/air	Yes	No	Yes	Yes
	Electric	(?)	No	Yes	Yes
05	**Bone Cutting Mechanism**				
	Straight, rigid blade	Yes	Yes	No	Yes
	High-speed rotation	No	No	yes	Yes
06	**Activation Recoil**	Yes	No	No	No
07	**Indicated for Skull/Spine Procedures**	Yes	Yes	Yes	Yes
08	**Protection of Surrounding Tissues**	Yes	Yes	Yes*	Yes
		* When used with a shielded attachment			
09	**Similarity in Materials**	Yes	Yes	Yes	Yes
		* Patient contact components			
10	**Indicated for Spine/Skull Procedures**	Yes	Yes	Yes	Yes
11	**Reusable Device**	Yes	Yes	Yes	Yes*
		* PKS Cutters are single-use, disposable devices			
12	**Cutting Blade Sharpness Assurance**	None	None	Yes*	Yes*
		* All Anspach Cutters are single-use, disposable devices			
13	**Cleaning Immersable**	No	(?)	No	No
14	**Recommended Sterilization Method**	Steam	Steam	Steam	Steam

End Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2002

The Anspach Effort, Inc.
William G. Conety
Director, Regulatory Affairs
4500 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K022907
Trade/Device Name: Anspach Powered Kerrison System (PKS)
Regulation Number: 882.4845
Regulation Name: Powered rongeur
Regulatory Class: Class II
Product Code: HAD
Dated: August 26, 2002
Received: September 3, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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: K022907

Device Name: "Powered Kerrison System" (PKS)

INDICATIONS FOR USE:

The Anspach Powered Kerrison System" (PKS) is indicated for use as an accessory attachment for Anspach Surgical Motor Systems for cutting, shaping and removal of bone, including bones of the skull and spine.

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 K022907

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