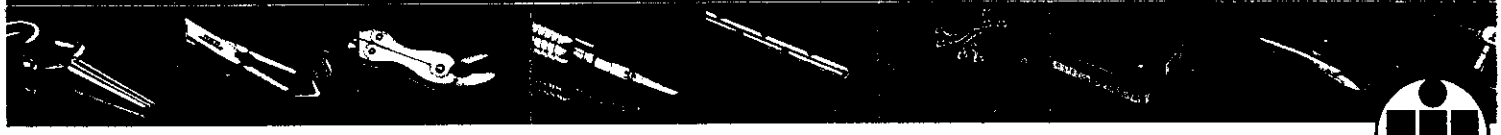

JAN 13 2005

Medicon Instrumente
the art of surgery

Medicon eG
Traditional 510(k) - HBB

K042974

2.

510(k) SUMMMARY
of Safety and Effectiveness
+
SE Comparison Table

Medicon eG
[As required by Section 807.92)]

2.1 **Submitter:** [807.92 (a)(1)]

Medicon eG
Gänsäcker 15
D-78532 Tuttlingen
Germany

Tel. +49 7462 2009 0
Fax +49 7462 2009 50
eMail sales@medicon.de
marketing@medicon.de

2.2 **Date Summary Prepared:** [807.92 (a)(1)]
September 2004

2.3 Device Names: [807.92(a)(2)]

Proprieatary	MEDICON VIPAIR Pneumatic High Speed System
Common	VIPAIR System
Device	Motor, Drill, Pneumatic
Device Description	Pneumatic cranial drill motor
Product Code	HBB
Device Class	Class II

2.4. Reason for Submission: [807.81(2)]

New Device

2.5 Predicate Device [807.92(a)(3)]

The Medicon High Speed Systems claims equivalence to the following system:

Zeppelin ZMM 200 Millenium Motordrill System (K013091)
Zeppelin Motordrill System (K92229)
Aesculap HiLan Motor System for Neurosurgery (K980686)
Komet Medical Xk – 95 Perforator Motor (K991625)
Midas Rex Legend System (K020069)
Midas Rex, Midas Rex I, II (K950518)
Sodem Powered Surgical Drill (K023066)
Black Max by Anspach (K930660)
Micromax by Anspach (K965080)

2.6 Device Describtion [807.92(a)(4)]

The Medicon VIPAIR pneumatic high speed system is specially designed for cutting and drilling of cranial and spinal bones. This system combines security and precision in an ergonomic design. The latest technology allows a reduction of the noise level to a minimum. The System consists of a small handpiece motor, a motor air tube, a foot control, a wall air tube, various hand pieces, craniotoms , burs, drills and cutters. The system components connect to each other via a safety coupling mechanism.

2.7 Intended Use: [807.92 (a)(5)]

The Medicon VIPAIR high speed system is a pneumatically operated motor system. The VIPAIR motor system provides power to operate removable rotating surgical tools like burs, cutters and drills intended for use in neurosurgery, including craniotomy and spinal surgery; as well as general surgical applications.

2.8 Environment of Use

The MEDICON VIPAIR high speed system are intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers.

Within these facilities the MEDICON VIPAIR high speed system may be located in areas where sterile surgical/dental instruments are used such as operating rooms for surgery.

2.9 Difference in Design and Technological Characteristics when Compared to SE Devices

[807.92(a)(6)]

Material: Patient contact materials for all High Speed Systems consist of surgical stainless steel

Design: The design is very similar between the systems. All High Speed Systems consists of hand piece motor, a motor air tube, a foot control, a wall air tube, various hand pieces, craniotoms, burs, drills and cutters.

2.10 Industry Standards: [807.92 (d)]

No applicable industry standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Medicon VIPAIR high speed system is manufactured accordance the MDD 93/42 EEC (please find Certificate from the notified body), the ISO and the German DIN Standards. Furthermore, the Medicon e.G. has received EN ISO 13485-2003 certification.

Substantially Equivalent

2.11 Information Bearing on the Safety and Effectiveness:

[807.92 (b)(3)]

The MEDICON VIPAIR system have the same intended use as predicate pneumatic motor systems. They are made of identical material **(Patient contact material)**. The slight differences in design and size do not adversely affect the safety and effectiveness of this device.

2.12 Comparison with predicate devices (table)

The Medicon VIPAIR High Speed System (Pneumatic) including cutting tools and accessories claims substantial equivalence to other currently marketed high speed pneumatic motor systems. This claim is based on equivalence in:

INTENDED USE

The Medicon VIPAIR High Speed System (Pneumatic) including cutting tools and accessories are used for the same clinical applications and intended use (Neurology) as the currently marketed high speed pneumatic motor systems.

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	YES	YES	YES	YES

METHODS OF STERILIZATION / STERILITY STATUS

Steam Sterilization Processes (DIN 58953-9) :
134° C, 2 bar, induction time at least 5 minutes, or 121° C, 1 bar, induction time at least 15 minutes.
All systems are supplied non-sterile, requiring reprocessing between surgical applications. Sterilization of all systems is accomplished using steam (see above). All systems require decontamination after use, and resterilization by the user facility.

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	YES	YES	YES	YES

MATERIAL

Patient contact materials for all systems consists of surgical stainless steel.
(Stainless Steel after DIN ISO 7153-1)

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	YES	YES	YES	YES

SYSTEM DESCRIPTION

Motor
All cited systems are operated using a pneumatic power source controlled by a foot pedal. For all systems, user can increase or reduce speed with foot pedal. The nominal power output of the Medicon VIPAIR is identical or substantially equivalent to the other commercially available pneumatic motor systems. The drill speeds are adjustable from 0 up to

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach	
100.000	90.000	95.000	95.000	85.000	80.000	80.000	RPM

Pressure
All cited systems operated using as power sources: air supply

The operating pressure is as follow:

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach	
90-120	90-120	~120	120-150	20-120	90-120	-120	PSI

Hand pieces and Accessories
The Medicon VIPAIR system and the other commercially available pneumatic motor systems includes straight and curved hand pieces as well as craniotoms. Furthermore all offer a wide variety of accessories including burs, drills and cutters.

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	YES	YES	YES	YES

Industry Standards
The Medicon VIPAIR System and the other cited systems are after the MDD 93/42 EEC (European Medical Device Directive) a Class IIA product. That means that the notify body has to examine the product and the DMF (Device Master File) before selling the product in the European Community.

CE Certificate after examination through the notify body according to the MDD 93/42 EEC

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	not known	YES	YES	YES

The companies of all cited Systems are certified after DIN ISO 9001:2000 or EN ISO 13485-2003

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	not known	YES	YES	YES

Furthermore the companies fulfil the MPG (German Medical Product Law)

Medicon	Aesculap	Zeppelin	Komet	Midas Rex	Sodem	Anspach
YES	YES	YES	not known	YES	YES	not known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Mr. Joachim Schmid
General Manager
Medicon eG
Gänsäcker 15
D-78532 Tuttlingen
Germany

Re: K042974
Trade/Device Name: Medicon VIPAIR High Speed System
Regulation Number: 21 CFR 882.4370
Regulation Name: Pneumatic cranial drill motor
Regulatory Class: II
Product Code: HBB
Dated: October 22, 2004
Received: November 10, 2004

Dear Mr. Schmid:

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/industry/support/index.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 K042974

Device Name **Medicon VIPAIR high speed system**

Classification **Motor, Drill, Pneumatic**

Product Code **84 HBB** **Class II** **21 CFR 882.4370**

INDICATIONS FOR USE

The Medicon VIPAIR high speed system is specially designed for cutting and drilling of cranial and spinal bones in the Neurology. Thanks to a wide variety of working attachments and tools, the Medicon pneumatic high speed system "VIPAIR" can be also used in the ENT and Orthopaedics.

The Medicon VIPAIR high speed system are intended for use and handling by professional and qualified Neurology , ENT or Orthopaedic surgeons.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per CFR 801 109) (Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K042974