PREMARKET NOTIFICATION [510(k)] SUMMARY K013091

A. SUBMITTER INFORMATION:

Date of summary: 09-10-01 JAN 2 5 2002

Submitted by:

VON ZEPPELIN
CHIRURGISCHE INSTRUMENTE GMBH
Gistlstrasse 99
82049 Pullach- Germany -
Tel.: +49 / 89 / 7936880
Fax: +49 / 89 / 7938545

Establishment registration no.: 8010947

Contact person: Mr. von Zeppelin, President

B. DEVICE INFORMATION:

Trade Name Aneurysm Clips: ZMM 2000
Zeppelin Millenium Motordrill System

Trade Name Parts:

ZMM-100	Motordrill Handpiece
ZMN-SI	Nosepiece attachment small
ZMN-VI	Nosepiece attachment, medium
ZMN-BL	Nosepiece attachment, large
ZMN-BA	Nosepiece attachment, X-large
ZMN-RE	Nosepiece attachment, XX-large
ZMC-01	Craniotome, small
ZMC-02	Craniotome, medium
ZMC-03	Craniotome, large
ZMW-110	Motor Tubing
ZMW-121	Wall Tubing

Common Name: Pneumatic Cranial Drill Motor

Class of Device: Class II

Classification Name: Cranial Drill Motor

Equivalent Device: Zeppelin Motordrill System *(#K92229)*
Aesculap HiLan Motor System for Neurosurgery *(#K980686)*
Midas Rex, Midas Rex I, II *(#K950518)*
Komet Medical Xk –95 Perforator Motor *(#991625)*
Black Max by Anspach

C. DEVICE DESCRIPTION:

The ZMM 2000 Zeppelin Millenium Motordrill System consists of a small handpiece motor, a motor air tube, a foot control, a wall air tube, various nosepieces and craniotoms and burs. The system components connect to each other via a proprietary coupling system.

D. INTENDED USE OF DEVICE:

The ZMM 2000 Zeppelin Millenium Motordrill System is a fast turning (~90.000 rpm) pneumatic powered surgical drill system for the rapid trepanation and resection of bone, plastic, metal or cement with high precision. It is in particular usefull to rapidely cut bone in neurosurgical procedures.

E. TECHNOLOGICAL CHARACTERISTICS

The ZMM 2000 is a variation and very much similar to the old Zeppelin Motordrill System with 510(k) Number: *#K922299* submitted in July 1992.

F. PERFORMANCE STANDARDS

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Zeppelin´s ZMM 2000 Zeppelin Millenium Motordrill Sytem is manufactured in accordance with ISO and German DIN Standards. Furthermore, the Zeppelin GmbH has received ISO 9001 certification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Von Zeppelin Chirurgische Instrumente GMBH
Dieter von Zeppelin
President
Gistlstrasse 99
82049 Pullach
Germany

Re: K013091
Trade Name: ZMM 2000 Zeppelin Millennium Motordrill System
Regulation Number: 882.4370
Regulation Name: Pneumatic Cranial Drill Motor
Regulatory Class: II
Product Code: HHB
Dated: December 18, 2001
Received: January 15, 2002

Dear Mr. von Zeppelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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" (21CFR 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,

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 (if known): (K013091)

Device Name : **ZMM 2000 Zeppelin Millenium Motordrill System**

Indication For Use:

INDICATION FOR USE STATEMENT:
The „ZMM 2000 Zeppelin Millenium Motordrill System" is a fast running (~90.000 rpm) powered surgical drill system for the rapide trepanation of bone, plastic, metal or cement with high precision. It is in particular usefull to rapidly cut bone in neurosurgical, ENT, maxillofacial and orthopedic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTIMUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓ OR Over-The-Counter USE _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milham
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013091