JAN 18 2006

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

K053526

Microspeed Uni Motor System
December 16, 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Microspeed Uni Motor System

COMMON NAME: Electric Surgical Motor System

CLASSIFICATION NAME: Motor, Drill, Electric

REGULATION NUMBER: 882.4360

PRODUCT CODE: HBC

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Microspeed Uni Motor System is substantially equivalent to:

- Aesculap Microspeed EC (K003612)
- Stryker Total Performance System (K943589)

DEVICE DESCRIPTION

The Microspeed Uni is an electronic, high-speed motor system, which allows high-speed dissection up to 80,000 rpm while also allowing low speed cutting up to 40,000 rpm. The control system reduces heating to a minimum at high torque.

The low speed motor can make use of all Aesculap Intra-handpieces (K953968) for adapted power at minimum weight. All HiLAN (K980686 and K973736) and Microspeed (K003612) handpieces can also be used for high-speed dissection with the Microspeed Uni. This allows universal use of one motor system during the entire procedure.

All functions of the Microspeed Uni can be controlled from the sterile field by the foot control as well as the hand control for easy handling.

INDICATIONS FOR USE

Aesculap's Microspeed Uni is intended for high speed cutting, sawing, drilling and manipulation of soft tissue and bone in the fields of Spine, ENT, Neuro and Maxillofacial Surgery.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The Microspeed Uni Motor System offers similar operating speeds, power sources, and attachments as the predicate devices. The material used for the Aesculap Microspeed Uni Motor System is the same or similar as that used to manufacture the predicate devices.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system. Aesculap's Motor System, however, complies with the following standards which appear on the FDA list of Recognized Consensus Standards:

IEC60601-1:	International electrotechnical commission: Medical electrical equipment Part 1: general requirements for safety
IEC60601-1-2:	International electrotechnical commission: Medical electrical equipment Part 1: general requirements for safety; collateral standard: Electromagnetic compatibility – requirements and tests
UL2601-1:	Underwriters laboratories; medical electrical equipment, general requirements for safety
	In addition, the Microspeed Uni Motor System meets the requirements of the following Canadian Standard Association standard.
	CAN/CSA-C22.2 Medical Electrical Equipment, Part 1: General No. 601.1-M90 Requirements for Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Ms. Kathy A. Racosky
Regulatory Affairs Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K053526
Trade/Device Name: Microspeed Uni Motor System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: II
Product Code: HBC
Dated: December 16, 2005
Received: December 21, 2005

Dear Ms. Racosky:

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,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K053526

Device Name: Microspeed Uni Motor System

Indications for Use:

Aesculap's Microspeed Uni is intended for high speed cutting, sawing, drilling and manipulation of soft tissue and bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053526