510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

CRANIOCUT

September 4, 2002 OCT 21 2002

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Georg Keller, Regulatory Affairs Manager
800-258-1946 (phone)
610-231-3713 (fax)
georg.keller@aesculap.com (email)

TRADE NAME: Craniocut

COMMON NAME: Cranial Trephine

DEVICE CLASS: CLASS II

PRODUCT CODE: 84HBE

CLASSIFICATION: 882.4310 – Powered simple cranial drills, burrs, trephines and their accessories

REVIEW PANEL: Neurology

INTENDED USE

Aesculap's **Craniocut** is intended for use in cutting bone in craniotomies.

DEVICE DESCRIPTION

Aesculap's Craniocut is an oscillating hollow saw. It consists of the Craniocut handpiece with adjustable depth stop and the disposable trephine. The Craniocut is to be operated at maximum 20,000 rpm and can be connected to Aesculap power systems like the Microspeed EC or HiLan Motor Systems.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for Craniocut.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

SUBSTANTIAL EQUIVALENCE

The new Craniocut described in this premarket notification is substantially equivalent to these predicate devices:

- Aesculap HiLan Motor System for Neurology (K980686)
- Aesculap Microspeed EC Motorsystem (K003612)
- MicroAire 1000E System (K014060)
- Komet XK095 High Speed Drill System (K984035)
- Anspach Angled Micronose Attachment (K002903)
- Anspach eMax Drill System (K011444)
- Midas Rex Legend System (K020069)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 2002

Aesculap, Inc.
Georg Keller
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K022942
Trade/Device Name: Craniocut
Regulation Number: 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines and accessories
Regulatory Class: II
Product Code: HBE
Dated: September 4, 2002
Received: September 5, 2002

Dear Mr. Keller:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K022942

Device Name: Craniocut

Indication for Use:

Aesculap's **Craniocut** is intended for use in cutting bone in craniotomies.

(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 21 CFR 801.109)

(Optional Format 3-10-98)

Miriam C. Provost

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

510(k) Number K022942