510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

CONTACT: Matthew M. Hull, Regulatory Affairs Manager
800-258-1946 (phone)
610-791-6882 (fax)
matt.hull@aesculap.com (email)

TRADE NAME: Aesculap Absorbable CranioFix

COMMON NAME: Cranioplasty plate fastener

DEVICE CLASS: CLASS II

PRODUCT CODE: HBW

REGULATION: 882.5360

REVIEW PANEL: Neurology

INTENDED USE

Aesculap's Absorbable CranioFix is intended for fixation of cranial bone flaps.

DEVICE DESCRIPTION

Aesculap's Absorbable CranioFix consists of two absorbable discs connected by a suture loop.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Aesculap Absorbable CranioFix.

PERFORMANCE STANDARDS

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

SUBSTANTIAL EQUIVALENCE

The Aesculap Absorbable CranioFix as described in this premarket notification is substantially equivalent to these predicate devices:

- Synthes Resorbable Cranial Clamp (modified) (K031654)
- Synthes Resorbable Cranial Clamp (K021408 and K031654)
- MacroPore CraniLoc NS (K002334)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

Mr. Matthew M. Hull
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K040080
Trade/Device Name: Aesculap Absorbable CranioFix
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr hole cover
Regulatory Class: II
Product Code: GXR
Dated: January 14, 2004
Received: January 15, 2004

Dear Mr. Hull:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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): K040080

Device Name: Absorbable CranioFix

Indication for Use:

Aesculap's Absorbable CranioFix is intended for fixation of cranial bone flaps.

Prescription Use X 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)

for Mark N Milhous

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

510(k) Number K040080

(Optional Format 3-10-98)