K091692

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

Aesculap PEEK Craniofix
August 10, 2010

AUG 12 2010

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

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: Aesculap PEEK CranioFix

COMMON NAME: Burr Hole Cover

CLASSIFICATION NAME: Cover, Burr, Hole (GXR)

REGULATION NUMBER: 882.5250

SUBSTANTIAL EQUIVALENCE
The Aesculap PEEK CranioFix as described in this premarket notification is substantially equivalent to the following predicate device:

- Aesculap Absorbable Craniofix (K040080)

DEVICE DESCRIPTION
Aesculap's PEEK CranioFix consists of two absorbable discs connected by a suture loop.

INDICATIONS FOR USE
Aesculap's PEEK CranioFix is intended for fixation of cranial bone flaps.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))
The Aesculap PEEK Craniofix has similar characteristics in design features (size, shape, function) and is considered substantially equivalent to the previously cleared predicate device on the market (K040080). The only change to the new device when compared to the predicate is a change in material.

All materials used in the manufacturing of the PEEK Craniofix are well recognized in their use as being biocompatible materials for implants and have been used in surgical procedures for many years. These materials have been accepted in previously cleared submissions.

K091692

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. This device has been evaluated and performs in accordance with ASTM F452/ASTM F2026. The subject device was found to be similar in performance to previously cleared spinal systems with similar indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap®, Inc.
c/o Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

AUG 12 2010

Re: K091692
Trade/Device Name: Aesculap PEEK CranioFix
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: June 14, 2010
Received: June 15, 2010

Dear Ms. Boyle:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AUG 12 2010

A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091692

Device Name: PEEK CranioFix

Indication for Use:

Aesculap's PEEK 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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

(Optional Format 3-10-98)

510(k) Number K091692