K122353

D. SPECIAL 510(k) SUMMARY
CRANIOFIX 2 TITANIUM CLAMP SYSTEM

AUG 30 2012

August 3, 2012

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

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TRADE NAME: CranioFix 2 Titanium Clamp System

COMMON NAME: Plate, Cranioplasty, Preformed, Non-alterable

REGULATION: Preformed non-alterable cranioplasty plate

PRODUCT CODE: GXN

REGULATION: 882.5330

REVIEW PANEL: Neurology

INTENDED USE

Aesculap's CranioFix 2 System is intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

DEVICE DESCRIPTION

The CranioFix 2 Clamp System consists of sterile, titanium implants (Clamps) and associated manual instruments. The Clamps are available in three sizes: 11mm, 16mm, and 20mm. The clamp consists of two concave disks which are connected with a pin through the center. The pin is securely attached to the lower disk; the upper disk is loosely mounted onto the pin. Each disk has rows of teeth extending along the edge of the concave side. The disks are mounted onto the pin with the teeth of each one facing the teeth of the other. The CranioFix 2 Titanium Clamps have a sleeve securely attached on the end of the pin. During the fixation, the lower disk comes to rest against the inner surface of the cranium and the upper disk comes to rest against the outer surface of the cranium.

TECHNOLOGICAL CHARACTERISTICS (Compared to Predicate)

The CranioFix 2 Clamp System has the same form, function, and material composition as the predicate CranioFix 2 Clamp System. Several minor modifications were made to the design of the device in order to enhance securement of the top disc and for manufacturability purposes.

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PURPOSE FOR SUBMISSION

The purpose for this special 510(k) submission is to gain marketing clearance for minor modifications to Aesculap's CranioFix 2 Clamp System.

PERFORMANCE DATA

Mechanical testing was performed to ensure that the modified device demonstrated equivalent tensile strength to the predicate CranioFix 2 device.

SUBSTANTIAL EQUIVALENCE

Risk analysis and performance testing demonstrate that the device modifications described in this premarket notification do not raise new questions of safety or effectiveness and therefore are substantially equivalent to the predicate device:

Aesculap CranioFix and CranioFix 2 Titanium Clamp System cleared via K040864.

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. Denise R. Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

AUG 30 2012

Re: K122353
Trade/Device Name: CranioFix 2 Titanium Clamp System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: August 3, 2012
Received: August 3, 2012

Dear Ms. Adams:

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

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,

Jessica Alexander

for

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

K122353

A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122353

Device Name: CranioFix 2 Titanium Clamp System

Indication for Use:

Aesculap's CranioFix 2 System is intended for use in the fixation of cranioplasty plates, covering burr holes, and fixation of cranial fractures.

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

510(k) Number K122353