K972332

AESCULAP®

JAN 16 1998

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Aesculap CRANIOFIX Titanium Clamp System

October 16, 1997

Submitted by: Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080
Contact: Mary Ellen Holden
Phone: (650) 876-7000 x348
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Product: Aesculap CRANIOFIX Titanium Clamp System
Common Names: Burr Hole Cover and Associated Nonpowered neurosurgical instruments

Intended Use

Aesculap's CRANIOFIX Titanium Clamp System is intended for use in refixation of cranial bone flaps after craniotomy.

Device Description

The CRANIOFIX Titanium Clamp System consists of a sterile, titanium implant (CRANIOFIX Clamp) and associated nonpowered neurosurgical instruments. The CRANIOFIX Titanium Clamp (FF100T) consists of two 10mm 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. During the craniotomy refixation, the lower disk comes to rest against the inner surface of the cranium and the bone plug. The upper disk comes to rest against the outer portion of the cranium and bone plug.

Technological Characteristics

The CRANIOFIX Titanium Clamp presses the bone cover and the vault of the cranium between the two disks. The implant is fixed to the cranium by means of special CRANIOFIX nonpowered neurosurgical instrument. It shares similar technological characteristics with titanium mini-plates which are attached to the cranium with bone screws. The main difference between CRANIOFIX and the comparative devices is the means of application.

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the CRANIOFIX Titanium Clamp System will be manufactured in accordance with ISO and German Din Standards. Furthermore, Aesculap AG has received ISO 9001 certification.

Substantial Equivalence

Aesculap's CRANIOFIX Titanium Clamp System shares similar features and function with corresponding devices distributed by:

- Aesculap
- KLS Martin
- Leibinger
- Zimmer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Ms. Mary Ellen Holden
Regulatory Compliance Associate
Aesculap, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K972332
Aesculap CranioFix Titanium Clamp System
Regulatory Class: II
Product Code: GXN
Dated: October 16, 1997
Received: October 20, 1997

Dear Ms. Holden:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K972332

Device Name:

Aesculap CRANIOFIX Titanium Clamp System.

Indication for Use:

Aesculap's CRANIOFIX Titanium Clamp System is intended for use in refixation of cranial bone flaps after craniotomy.

(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 Devices
510(k) Number K972332

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)