

OCT 08 2008

Confidential

MAYFIELD® MR/X-Ray Skull Clamp

510(k) Summary

K081401

Submitter's name and address:

Integra LifeSciences Corporation
4900 Charlemer Drive, Building A
Cincinnati, Ohio 45227 USA

Contact person and telephone number:

Helder A. Sousa
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
(609) 936-6850

Date prepared: May 16, 2008

Name of device:

Proprietary Name: MAYFIELD® MR/X-Ray Skull Clamp
Common Name: Skull Clamp
Classification Name: Neurological Head Holder

Substantial Equivalence:

The MAYFIELD® MR/X-Ray Skull Clamp is substantially equivalent in function and intended use to the unmodified MAYFIELD® MR/CT Skull Clamp which has been cleared to market under Premarket Notification 510(k) K050319.

Indications Use:

The MAYFIELD® MR/X-Ray Skull clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. In addition, the clamp is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques.

Device Description:

The MAYFIELD® MR/X-Ray Skull Clamp is designed to provide rigid skeletal fixation for procedures involving imaging modalities, such as intra-operative MR, CT, and digital subtraction angiography. The Skull Clamp is designed for patient positioning in the prone or supine positions. The Skull Clamp requires the use of three (3) each Skull Pins. Avoidance of critical areas of the skull is made possible by a swiveling rocker arm which rotates 360°. In addition, the swiveling rocker arm can rotate 360° under full skeletal force.

Conclusion:

The modified MAYFIELD® MR/X-Ray Skull Clamp is substantially equivalent to the unmodified MAYFIELD® MR/CT Skull Clamp (K050319). The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.



OCT 08 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
% Helda A. Sousa
Regulatory Affairs Project Manager
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K081401

Trade/Device Name: MAYFIELD® MR/X-Ray Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: September 5, 2008
Received: September 8, 2008

Dear Helda A. Sousa:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081401

Device Name: **MAYFIELD® MR/X-Ray Skull Clamp**

Indications For Use:

The MAYFIELD® MR/X-Ray Skull clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. In addition, the clamp is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil B. Ogden for me
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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