MAR 3 1 2005

Mayfield® MR/CT Skull Clamp

510(k) Summary

K050319

Submitter's name and address:

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

Contact person and telephone number:

Charles E. Dinkler II
Director New Product Development
(513) 533-7979

Date prepared: March 22, 2005

Name of device:

Proprietary Name:	Mayfield® MR/CT Skull Clamp
Common Name:	Head Holder or Skull Clamp
Classification Name:	Neurological Head Holder

Substantial Equivalence:

The Mayfield® MR/CT Skull Clamp is substantially equivalent to the Mayfield® Radiolucent Skull Clamp.

Indications Use:

The Mayfield® MR/CT 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 us 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/CT Skull Clamp is designed to provide rigid skeletal fixation for procedures involving all imaging modalities, intra-operative MR, CT and digital subtraction angiography. The Skull Clamp is designed for patient positioning in the prone or supine positions. The design of the Skull Clamp allows the surgeon more freedom in positioning the fixation 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, making final positioning after pin impingement easier. The lean body design of the Mayfield® MR/CT Skull Clamp also allows for greater exposure to the operative site.

Conclusion:

The Mayfield® MR/CT Skull Clamp is substantially equivalent to the commercially marketed predicate device and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Mr. Charles E. Dinkler II
Director New Product Development
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, Ohio 45227

Re: K050319
Trade/Device Name: Mayfield MR/CT Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurological head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: March 3, 2005
Received: March 4, 2005

Dear Mr. Dinkler:

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.

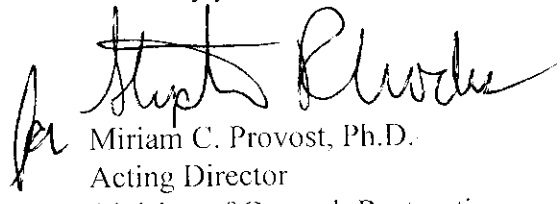
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K050319

Device Name: Mayfield MR/CT Skull Clamp

Indications For Use:

The Mayfield MR/CT 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___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K050319