K051440

SEP 2 0 2005

Mayfield® Infinity Skull Clamp
510(k) Summary

Submitter's name and address:

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

Contact person and telephone number:

Donna R. Wallace
Director Regulatory Affairs
(609) 936-2397

Date prepared: May 24, 2005

Name of device:

Proprietary Name:	Mayfield® Infinity Skull Clamp
Common Name:	Head Holder or Skull Clamp
Classification Name:	Neurological Head Holder

Substantial Equivalence:

The Mayfield® Infinity Skull Clamp is substantially equivalent to the Modified Mayfield® Skull Clamp, Mayfield A2000 Skull Clamp, and the DORO® Skull Clamp.

Indications Use:

The Mayfield® Infinity 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. The accessories provided with the skull clamp also allow it to be used where stabilization is desired instead of complete fixation.

Device Description:

The Mayfield® Infinity Skull clamp is designed to be a multifunctional cranial stabilization/fixation device. It's basic configuration delivers standard Mayfield Skull Clamp performance. The accessories enhance the clamp's capability and enable it to provide rigid skeletal fixation in conjunction with the Infinity Support System. The contours and length of the skull clamp uprights allow the clamp to maintain a lower profile than standard clamps. When this clamp is used to provide auxiliary skeletal fixation, the Reduced Load Torque Screw may be used for procedures that demand lower pin impingement forces. The device allows the surgeon to select the most suitable combination of components for each procedure and is designed to allow the surgeon freedom in positioning the fixation pins. Avoidance of critical areas of the skull is facilitated by a swiveling rocker arm that also rotates 360°. To simplify patient re-positioning after pin impingement, the rocker may be rotated without adjustment of the impingement force imposed by the Torque Screw.

Conclusion:

The Mayfield® Infinity 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

SEP 2 0 2005

Ms. Donna R. Wallace, RAC
Director Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K051440
Trade/Device Name: MAYFIELD® Infinity Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: September 9, 2005
Received: September 12, 2005

Dear Ms. Wallace:

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/dsma/dsmamain.html

Sincerely yours,

Barbara Brenner for

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

Enclosure

Indications for Use

K051440

510(k) Number (if known):

Device Name: MAYFIELD® Infinity Skull Clamp

Indications For Use:

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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)

Barbara Burkhart

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

510(k) Number K051440