NOV 2 1 2005

K053045

Mayfield® Radiolucent Skull Pins
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
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
(609) 936- 2397

Date prepared: October 20, 2005

Name of device:

Proprietary Name:	Mayfield® Radiolucent Skull Pins
Common Name:	Skull Pins
Classification Name:	Neurological Head Holder

Substantial Equivalence:

The Mayfield® Radiolucent Skull Pins are substantially equivalent in function and intended use to the unmodified Mayfield® Radiolucent Skull Pins which have been cleared to market under Premarket Notification 510(k) K021604.

Indications Use:

The Mayfield® Radiolucent Skull Pins are intended for use with a skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative CT or MR imaging is used.

The Mayfield® Radiolucent Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative CT or MR imaging of the patient is used.

Device Description:

The Mayfield® Radiolucent Skull Pins are single use devices which are used with Mayfield® Skull Clamps for approaches that require rigid skeletal fixation. In preparation for surgery three Radiolucent Skull Pins are installed in a Mayfield® Skull Clamp. Two Radiolucent Skull Pins are inserted in the Rocker Arm side of the Clamp and a single Radiolucent Skull Pins is inserted on the opposite side. The Mayfield® Radiolucent Skull Pins may be used in surgical procedures when rigid fixation is desired and Intra-Operative CT or MR imaging is used.

Conclusion:

The modified Mayfield® Radiolucent Skull Pins is substantially equivalent to the unmodified Mayfield® Radiolucent Skull Pins. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K053045
Trade/Device Name: MAYFIELD® Radiolucent Skull Pins
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: October 27, 2005
Received: October 31, 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/industry/support/index.html.

Sincerely yours,

Barbara Bucher
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

510(k) Number (if known): K053045

Device Name: MAYFIELD® Radiolucent Skull Pins

Indications For Use:

The MAYFIELD® Radiolucent Skull Pins A-2020 are intended for use with a skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures when rigid skeletal fixation is desired and Intra-Operative CT or MR imaging is used.

The MAYFIELD® Radiolucent Skull Pins A-2020 are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative CT or MR imaging of the patient is used.

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)

Barbara Ann MD

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

510(k) Number K053045