K130389

Integra LifeSciences Corporation – Traditional 510(k)
MAYFIELD® Infinity XR2 Skull Clamp

APR 2 3 2013

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone number	609-936-5526
Fax number	609-275-9445
Establishment Registration Number	3003418325
Name of contact person	Aakash Jain
Date prepared	February, 12 2012
Manufacturing Site Information	
Name	Integra LifeSciences Corporation
Address	4900 Charlemar Drive, Bldg. A Cincinnati, OH 45227
Establishment Registration Number	3004608878
807.92(a)(2) - Name of device	
Trade or proprietary name	MAYFIELD® Infinity XR2 Skull Clamp
Classification name	Holder, Head, Neurosurgical (Skull Clamp)
Common or usual name	Neurosurgical head holder (skull clamp)
Classification panel	Neurology
Product Code(s)	HBL
Regulation Number	882.4460
Device Class	Class II
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	MAYFIELD® Infinity XR2 Skull Clamp (K090506)
807.92(a)(4) - Device description	
The MAYFIELD Infinity Skull Clamp is a cranial stabilization device, designed to provide rigid skeletal fixation. The MAYFIELD® Infinity XR2 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 skeletal fixation is necessary. The MAYFIELD Infinity XR2 Skull Clamp has not been modified since its clearance to market by United States Food and Drug Administration (FDA) on April 20, 2009 under K090506. The proposed MAYFIELD Infinity XR2 Skull Clamp is identical in every way to the currently marketed MAYFIELD Infinity XR2 Skull Clamp except for revised labeling which includes information regarding the safe use of this device when used in an MR environment and updated cleaning/decontamination instructions.	

807.92(a)(5) Intended use of the device	
Indications for use	The MAYFIELD® Infinity XR2 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 skeletal fixation is necessary. In addition, the clamp is indicated for use during utilization of imaging modalities such as intra-operative CT imaging, C-Arm x-ray, digital subtraction techniques, and MR imaging.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristics	**MAYFIELD Infinity XR2 Skull Clamp**	**Predicate: MAYFIELD Infinity XR2 Skull Clamp (K090506)**
Shape	Curved uprights	Same
Adjustment for various head sizes	Ratchet arm is adjustable	Same
Load Range	0-80 lbs	Same
80 lb force applicator	Yes	Same
Three point fixation	Yes	Same
Rocker Arm		
2 pin	Yes	Same
360° rotation under full impingement force	Yes	Same
Removable	Yes	Same
Secured using the swivel lock knob	Yes	Same
Child Rocker Arm	Yes (Interchangeable Child Rocker Arm Accessory)	Same
Hinged base plate	Yes	Same
Clamp Release	Plunger	Same
Multiple pawls	Yes	Same

Characteristics	MAYFIELD Infinity XR2 Skull Clamp	Predicate: MAYFIELD Infinity XR2 Skull Clamp (K090506)
Target Patient Population	Not recommended for children under 5 years of age	Same
Materials	PEEK / Carbon fiber composite Radel R (Polyphenylsulphone) Teflon Hastelloy Nylon Titanium 6ALV4 Polyamide-imide Viton	Same
Cleaning/ Decontamination	Intended to be used non-sterile. Intended to be cleaned by user between uses.	Same
	pH range 3-11 and high temperature	Neutral pH and high temperature
	Can be autoclaved Disinfection: Pre cycle vacuum at 2psia then steam disinfect at 132°C to 135°C for 3 minutes Decontamination: Immersion in each solution for 1 hour then autoclave at 134°C for 18 minutes to 1 hour	Can be autoclaved Disinfection: Pre cycle vacuum at 2psia then steam disinfect at 132°C to 135°C for 3 minutes
Where Used	Used in the operating room of the hospital. Also used in the diagnostic and or the intra-operative operating suite.	Same
Pins	Uses existing MAYFIELD Skull pins	Same
Accessories	Interchangeable Child rocker arm, Metal-free conversion accessory, Removable force applicator	Same

807.92(b)(1-2) NONCLINICAL TESTS SUBMITTED	
Test	**Result**
The Mayfield Infinity XR2 Skull Clamp is identical in design, performance, and materials of composition to the currently marketed predicate device. Since the proposed device is identical to the currently marketed device, all performance testing relating to the performance of the predicate device remains unchanged. Additional bench testing was performed to determine the safe use conditions for this	

product in an MR environment.	
ASTM F2052	No attraction to the magnet in either 1.5T or 3T
807.92(b)(3) CONCLUSIONS DRAWN FROM NON-CLINICAL DATA	
Testing demonstrated that the MAYFIELD Infinity XR2 Skull Clamp can be used in an MR Environment	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2013

Integra Lifesciences Corporation
c/o Ms. Janet Kay
Director, Regulatory Affairs
22 Terry Avenue
Burlington, MA 01803

Re: K130389
Trade/Device Name: Mayfield® Infinity XR2 Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 12, 2013
Received: February 15, 2013

Dear Ms. Kay:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K130389**

Device Name: **Mayfield® Infinity XR2 Skull Clamp**

Indications For Use:

The MAYFIELD® Infinity XR2 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 skeletal fixation is necessary.

In addition, the clamp is indicated for use during utilization of imaging modalities such as intra-operative CT imaging, C-Arm x-ray, digital subtraction techniques, and MR imaging.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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