K120633

510(k) SUMMARY

MAY 24 2012

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	609-936-5583
Fax number	609-275-9445
Establishment Registration Number	3003418325
Name of contact person	Lindsay Mignone
Date prepared	February 29, 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® 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 Skull Clamp is a cranial stabilization device, designed to provide rigid skeletal fixation. The MAYFIELD Skull Clamp supports a 2-pin rocker arm, which allows for 360° rotation under full impingement force. The device has the means for skull pin force

	determination via an integral force gauge in the torque screw opposite the rocker arm. The device is equipped with an adjustable ratchet arm to allow the surgeon to adjust the clamp for various head sizes. The ratchet arm is released by side-acting pawls, which facilitate the removal of the clamp from the patient. The MAYFIELD Skull Clamp is available in three configurations, including the base configuration, A-3059. The A-3059 C clamp is equipped with a child rocker assembly, and is suitable for patients with smaller head sizes. The A-3059 S clamp is equipped with an adjustment knob at the base of the clamp, which allows the user to limit free play between the clamp base and ratchet extension. The MAYFIELD Skull Clamp does not directly contact the patient. The MAYFIELD Skull Pins used with the skull clamp are the components which contact the patient. The skull pins are supplied separately and are not the subject of this 510(k). The MAYFIELD Skull Clamp is intended to be used non-sterile. It can be autoclaved and cleaned using detergents ranging from a pH of 3 to a pH of 11 as part of the cleaning and decontamination process.
807.92(a)(5) Intended use of the device	
Indications for use	The MAYFIELD 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.

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

Design	**MAYFIELD Skull Clamp**	**Predicate MAYFIELD Infinity XR2 Skull Clamp (K090506)**
Shape	Parallelogram	Curved uprights
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

	MAYFIELD Skull Clamp	**Predicate MAYFIELD Infinity XR2 Skull Clamp (K090506)**
Rocker Arm		
2 pin	Yes	Same
360° rotation under full impingement force	Yes	Same
Removable	No	Yes
Secured using the swivel lock knob	Yes	Same
Child Rocker Arm	Yes (Catalog No. A-3059 C only)	Yes (Interchangeable Child Rocker Arm Accessory)
Hinged base plate	No	Yes
Clamp Release	Side acting pawls	Plunger
Adjustment knob	Yes (Catalog No. A-3059 S only)	No
Multiple pawls	Yes	Same
Target Patient Population	Not recommended for children under 5 years of age	Same
Materials	PEEK / Glass fiber composite Radel R (Polyphenylsulphone) Teflon Hastelloy Stainless Steel Silicone	PEEK / Carbon fiber composite Radel R (Polyphenylsulphone) Teflon Hastelloy Nylon Titanium 6ALV4 Polyamide-imide Viton
Cleaning/ Decontamination	Intended to be used non-sterile. Intended to be cleaned by user between uses.	Same
	pH range 3-11 and high temps	Neutral pH – high temp
	Can be autoclaved Disinfection: Pre cycle vacuum at 2psia then steam disinfect at 132°C to 134°C for 4 minutes Decontamination: Immersion in bleach solution for 1 hour then autoclave at 134°C for 18 minutes to 1 hour	Same Disinfection: Pre cycle vacuum at 2psia then steam disinfect at 132°C to 135°C for 3 minutes
Imaging Modality	Non-radiolucent	Radiolucent

	MAYFIELD Skull Clamp	**Predicate MAYFIELD Infinity XR2 Skull Clamp (K090506)**
Where Used	Used in the operating room of the hospital. Also used in the diagnostic and or the intra-operative operating suite.	Same Same
Pins	Uses existing MAYFIELD Skull pins	Same
Accessories	None	Interchangeable Child rocker arm, Metal-free conversion accessory, Removable force applicator

807.92(b)(1-2) NONCLINICAL TESTS SUBMITTED	
Test	**Result**
Skull Clamp Gauge Characteristics – Establishes the characteristics of the integral force gauge on the skull clamp	**Pass** – The skull clamp was capable of indicating impingement force in increments of 20 lbs up to 80 lbs, and was accurate to within the ± 4 lb limit at each force graduation.
Skull Clamp Range – Determines the physical limits of the skull clamp adjustment	**Pass** – The clamp provided a range of positions from 4 inches through 9 inches.
Skull Clamp Static Load – Verifies the ability of the skull clamp to sustain an 80lb load to a 2x factor of safety	**Pass** – The clamp supported 160 lb for no less than 24 hours without mechanical failure.
Skull Clamp Load Loss – Verifies the ability of the skull clamp to maintain a user defined load in use	**Pass** – The clamp provided a static clamping force of 80 lbs for 24 hours without a loss of loading greater than 5%.
Skull Clamp Transient Torque – Verifies the ability of the skull clamp to resist transient torque while in use	**Pass** – The swivel locking mechanism was capable of withstanding a dynamic torque of 20 lb/ft for 30 seconds without mechanical failure.
Skull Clamp Static Torque – Verifies the ability of the skull clamp to resist applied torque while in use	**Pass** – The swivel locking mechanism was capable of withstanding a static torque of 10 lb/ft for 24 hours without slippage or mechanical failure.
Skull Clamp Vertical Shear – Verifies the ability of the skull clamp to support an applied vertical load	**Pass** – The loading mechanism was capable of withstanding a vertical shear loading of at least 100 lbs at 80 lbs pin loading.
Skull Pin Compatibility – Verifies compatibility of the skull clamp with MAYFIELD Skull Pins and Base Units.	**Pass** – The skull clamp demonstrated compatibility with MAYFIELD Skull Pins and the A3100 series of MAYFIELD Base Units.
Manual Cleaning Validation – Validates the effectiveness of the manual cleaning process on the skull clamp	**Pass** – The skull clamp demonstrated a protein level < 6.4 $\mu g/cm^2$ and hemoglobin < 2.2 $\mu g/cm^2$ following the manual cleaning process.

Low Level Disinfection Validation – Validates the effectiveness of the low level disinfection process on the skull clamp	**Pass** – The skull clamp demonstrated a 6 $\log_{10}$ reduction or better for *S. aureus, E. coli, K. pneumoniae and P. aeruginosa* following the low level disinfection process.
Thermal Disinfection Validation – Validates the effectiveness of the thermal disinfection process on the skull clamp	**Pass** – The skull clamp demonstrated a 6 $\log_{10}$ reduction or better for *S. aureus, E. coli, K. pneumoniae and P. aeruginosa* following the thermal disinfection process.
WHO Performance Test – Verifies the ability of the skull clamp to withstand repeated cycles of the WHO (World Health Organization) recommended guidelines for decontamination without mechanical failure	**Pass** – The skull clamp was capable of withstanding 15 cycles of the WHO decontamination process without mechanical failure.
Autoclave Preconditioning Test – Verifies the ability of the skull clamp to withstand repeated autoclave cycles without mechanical failure	**Pass** – The skull clamp was capable of withstanding 15 autoclave cycles of 134°C for 60 minutes, and passed all mechanical testing following autoclave preconditioning.
Shipping Verification Test – Verifies that the packaging for the skull clamp is capable of protecting the device during transit to ISTA Procedure 2A standards	**Pass** – The packaging for the skull clamp was not breached during the ship test. The skull clamp remained undamaged and passed all function checks during inspection.
Biocompatibility	No component contacts the patient; therefore, no biocompatibility studies are required
807.92(b)(3) CONCLUSIONS DRAWN FROM NON-CLINICAL DATA	
Testing confirmed that the performance of the MAYFIELD Skull Clamp meets the product specifications of the device.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Integra Life Sciences Corporation
c/o Ms. Lindsay Mignone
Regulatory Affairs Associate
311 Enterprise Dr.
Plainsboro, NJ 08536

MAY 24 2012

Re: K120633
Trade/Device Name: Mayfield A-3059, A-3059C, A-3059S Skull Clamp
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurological Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 29, 2012
Received: March 1, 2012

Dear Ms. Mignone:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120633

Device Name: Mayfield A-3059, A-3059C, A-3059S Skull Clamp

Indications for Use:

The Mayfield® 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 skull fixation is necessary.

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 LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120633