510(k) SUMMARY FOR HFD100

K103493

(As required by 21 CFR 807.92)

MAR 11 2011

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada, R3T 1N5
Registration Number:	3003807210
Contact Person:	Mr. Sanjay Shah QA and Regulatory Engineer Email: sshah@imris.com Phone: 1-204-480-7070 Fax: 1-204-480-7071
Date of Summary Preparation:	February 1, 2011
Device Name / Trade name	Head Fixation Device (HFD100)
Classification Name:	Neurosurgical head holder (skull clamp)
Classification Panel:	Radiology
Classification (CFR section):	21 CFR 882.4460
Class:	Class II
Product Code:	HBL

2. PREDICATE DEVICES

The HFD100 system is substantially equivalent to the following predicate medical devices.

NAME OF THE DEVICE	510(K) NUMBER	DATE OF CLEARANCE	MANUFACTURER
MAYFIELD® MR/X-Ray Skull Clamp	K081401	Oct 8, 2008	Integra LifeSciences corporation
MAYFIELD® Disposable and Reusable Titanium Skull Pins	K072208	Sep 7, 2007	Integra LifeSciences corporation
DORO® Radiolucent/MRI Compatible Cranial stabilization	K063494	May 21, 2007	Pro med instruments GmbH

3. DEVICE DESCRIPTION

The IMRIS Head Fixation Device System (HFD100) is an MR compatible mechanical support system intended to be used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

The HFD100 and its accessories are designed to immobilize the head during surgical procedures and support the patient in the prone, supine or lateral positions. The HFD100 system can be use with either the operating room table or the angiography room table. The IMRIS HFD100 consists of the Table Adapter, Linkage System, Skull Clamp and Skull Pins. The linkage system is used to mount the Skull Clamp (including 3 skull pins) to the table Adapter. The table adaptor is used to mount HFD100 on the table. The 3-point rigid cranial fixation device, skull clamp, provides multifunctional options for cranial stabilization and provides maximum immobilization of the patient's skull during the procedure. The HFD100 provides rigid skeletal fixation within the optimal imaging envelope during intraoperative procedure with minimal artifacts in the acquired images.

4. INDICATION FOR USE

The IMRIS Head Fixation Device System is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

5. COMPARISION TO PREDICATE DEVICES

Manufacturer	**Integra LifeSciences Corporation**	**Integra LifeSciences Corporation**	**Pro med instruments GmbH**	**IMRIS Inc.**
FDA 510(k) #	K081401	K072208	K063494	Subject Device (K103493)
Trade/Device Name	MAYFIELD® MR/X-Ray Skull Clamp	MAYFIELD ® Disposable and Reusable Titanium Skull Pins	DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories	HFD100
Product Code	HBL	HBL	HBL	HBL
FDA Classification	21 CFR 882.4460	21 CFR 882.4460	21 CFR 882.4460	21 CFR 882.4460

Indication for use	The MAYFIELD® MR/X-Ray 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.	The MAYFIELD® Disposable and Reusable Titanium Skull Pins are intended for use with a MAYFIELD 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 MR imaging is used. The MAYFIELD® Disposable and Reusable Titanium Skull Pins are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when Intra-Operative MR imaging of the patient is used.	**The Radiolucent MRI Compatible Skull Clamp Headrest System with Skull Pins** The DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins are components of a mechanical support system which is used in head and neck surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative CT or MR Imaging is used. **The Radiolucent / MRI Compatible Horseshoe Headrest System** The DORO® Radiolucent / MRI Compatible Horseshoe Headrest System are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required and when intra-operative CT or MR Imaging is used.	The IMRIS Head Fixation Device System is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE: (807.92 (A) (6))

CHARACTERISTIC	Integra LifeSciences Corporation MAYFIELD® MR/X-Ray Skull Clamp (K081401) and MAYFIELD® Disposable and Reusable Titanium Skull (K072208)	Pro med instruments GmbH DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories (K063494)	IMRIS Inc. HFD100	COMPARISION
Skull Clamp	3-Pin Skull clamp	3-Pin Skull clamp	3-Pin Skull clamp	Same
MRI system Compatibility	MRI compatible	MRI compatible	MRI compatible	Same
Material	Composite materials	NOVOTEX laminated fabric with phenolic resin (GRP) colored with BASANTOL black X82 liquid and POM (Delrin), PEEK and Polyurethan.	Titanium and Composite materials	Different
Mounting	Two pin mounting mechanism On Standard OR Table	Two pin mounting mechanism On Standard OR Table	Two pin mounting mechanism On IMRIS design OR table or Angio table	Different
Support load	20kg	12.5kg	20kg	Same (same as MAYFIELD® skull clamp)
Pin force	80lb	80lb	80lb	Same
Application	• General neurosurgical procedures • Intra-operative neurosurgical procedures	• General neurosurgical procedures • Intra-operative neurosurgical procedures	• General neurosurgical procedures • Intra-operative neurosurgical procedures	Same
Sterile Pins	Titanium MAYFIELD® Disposable and Reusable Titanium Skull Pins (K072208)	DORO® Radiolucent Disposable Single-Use Skull Pins or Titanium X-ray and MRI compatible.	Titanium Exactly the same as Integra LifeSciences Corporation Pins	Same (same as Integra LifeSciences Corporation Pins)

CHARACTERISTIC	Integra LifeSciences Corporation MAYFIELD® MR/X-Ray Skull Clamp (K081401) and MAYFIELD® Disposable and Reusable Titanium Skull (K072208)	Pro med instruments GmbH DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories (K063494)	IMRIS Inc. HFD100	COMPARISION
	Titanium Disposable Child Skull Pin A1119		Titanium Disposable Child Skull Pin A1119	Same
	Titanium Disposable Adult Skull Pin A1120		Titanium Disposable Adult Skull Pin A1120	Same
	Adult Skull Pin, Titanium A1121		Adult Skull Pin, Titanium A1121	Same
	Child Skull Pin, Titanium A1122		Child Skull Pin, Titanium A1122	Same

7. SUMMARY OF NON-CLINICAL DATA

Biocompatibility of Pins:

The skull pins used in the HFD100 are invasive. The skull pins meet ISO 10993-1:2003 (Biological Evaluation of medical devices) and relevant ISO 10993 series standards. The biocompatibility of pins has been verified by Integra LifeSciences Corporation in K072208.

There is no change made by IMRIS. Pins initially included are provided by Integra Life Sciences with their labeling. IMRIS does not relabel the pins. Pins are purchased from Integra LifeSciences Corporation directly.

Design Verification and Validation Test (Bench Testing)

The HFD100 system passed the following tests and meets product specifications.

- Loading test
- MR image artifacts test
- MR heating test
- Cleaning, marking and labeling requirements
- Marking durability
- Flammability requirement
- Usability requirements and workflow

8. CONCLUSION

The HFD100 has the same intended use and indications for use as the predicate devices. Performance data demonstrate safety and effectiveness of the HFD100 with the new characteristics.

The IMRIS HFD100 verification/validation results and performance/safety standard results show that the device is safe and effective and substantially equivalent to the currently available predicate devices, Integra LifeSciences MAYFIELD® MR/X-Ray Skull Clamp and Pro med instruments DORO® Radiolucent/MRI Compatible Cranial stabilization.

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

IMRIS, Inc.
c/o Mr. Sanjay Shah
QA and Regulatory Engineer
100-1370 Sony Place
Winipeg, Manitoba
Canada, R3T 1N5

MAR 11 2011

Re: K103493
Trade/Device Name: Head Fixation Device (HFD 100)
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical Head Holder (Skull Clamp)
Regulatory Class: Class II
Product Code: HBL
Dated: February 1, 2011
Received: February 2, 2011

Dear Mr. Shah:

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.

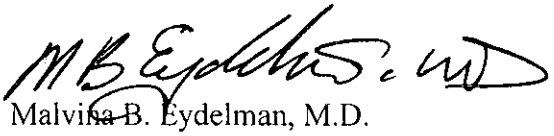
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

510(k) Number (if known): K103493

Device Name: Head Fixation Device (HFD100)

Indications For Use:

The IMRIS Head Fixation Device System is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.

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

CGI

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

510(k) Number K103493