K122456

510(k) Summary

MAR 2 2 2013

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the MRII Cranial Drill and accessories.

1. **Company Making the Submission:**

Name of Owner:	**MRI Interventions, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
Telephone:	**949-900-6833**
Fax:	**949-900-6834**
Contact:	**Edward Waddell**
E-mail:	**ewaddell@mriinterventions.com**

2. **Device Name:**

Common Name:	Manual Drill
Proprietary Name:	MRII Cranial Drill
Classification:	Class II
Regulation Number:	882.4300
Product Code:	HBG

3. **Predicate Device**
Integra Hand Drill, K961113

4. **Intendeded Use Statement:**

The MRII Cranial Drill and accessories is intended to provide access through the skull for ventriculostomy or other neurological procedures, such as biopsy or catheter placement, in or near an MR scanner of 3T maximum field strength. The MRII Cranial Drill and accessories are intended to be used only when the scanner is not performing a scan. The MRII Cranial Drill is intended for single use only.

5. **Description of Device:**
The MRII Cranial Drill is a hand held manual drill with a 3:1 gear ration. It is in intended for use with the drill kit accessory kits consisting of a 2.0 or 3.2 mm drill bit, lancet, depth stop and ruler.

6. **Summary of the Technological Characteristics of the Device Compared to the Predicate Device**

	MRII **MRII Cranial Drill**	**Predicate Device:** **Integra Hand Drill** **K961113**
Classification	21 CFR 882.4300	21 CFR 882.4300
Product Code	HBG	HBG
Intended Use	The MRII Cranial Drill and accessories is intended to provide access through the skull for ventriculostomy or other neurological procedures, such as biopsy or catheter placement, in or near an MR scanner of 3T maximum field strength. The MRII Cranial Drill and accessories are intended to be used only when the scanner is not performing a scan. The MRII Cranial Drill is intended for single use only.	The drill is intended to be used with an external drainage and monitoring system in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF and to monitor ICP. The drill is intended for single use only.
Environment	OR or MRI Suite	OR
Drill Bit Included with Drill	No	No
Gear Ratio	3:1	3.5:1
Integral Bit	Yes (316L SS)	Yes
Drill Bit Sizes	2.0mm 3.2mm	3/16" (4.7mm) 5/32" (3.97mm) 13/64" (5.31mm) ¼" (6.35mm)
Adjustable Depth Guard	Yes	Yes
Set Screw with Hex Wrench	No	No
Packaging	Drill: Sterile, CSR Warp in Tyvek Peel Pouch. Kit: Sterile, inside tray with Tyvek Lid and external	Sterile, CSR Wrap in Tyvek Peel Pouch

	MRII **MRII Cranial Drill**	**Predicate Device:** **Integra Hand Drill** **K961113**
	Tyvek Pouch	

7. Testing:

Testing to applicable standards has been completed with acceptable outcomes.

Bench testing performed included design verification testing and comparison testing with the predicate Integra Hand Drill, with acceptable results. These tests demonstrated that the MR Cranial Drill functions as intended and is substantially equivalent to legally marketed devices.

8. Rx or OTC:

The MRI Cranial Drill is an Rx prescription device per 21 CFR Part 801, Subpart D.

9. Substantial Equivalence:

The MR Cranial Drill is as safe and effective as the predicate Integra Hand Drill. The MR Cranial Drill has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the MR Cranial Drill and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the MR Cranial Drill is as safe and effective as the Integra Hand Drill. Thus, the MRI Cranial Drill is substantially equivalent.

MRI Interventions, Inc.

Edward Waddell
Director of Regulatory Affairs

Date: 11/13/12

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

March 22, 2013

MRI Interventions, Inc.
Mr. Edward Waddell
5 Musick
Irvine, CA, 92618

Re: K122456
Trade/Device Name: MRII Cranial Drill
Regulation Number: 21 CFR 882.4300
Regulation Name: Manual Cranial Drills, Burrs, Trephines, and their accessories
Regulatory Class: Class II
Product Code: HBG
Dated: February 15, 2013
Received: March 7, 2013

Dear Mr. Waddell:

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,

Joyce M. Whang

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 (if known): K122456

Device Name: MRII Cranial Drill

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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

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

510(k) Number K122456