



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 8, 2015

MRI Interventions, Inc.
Mr. E. F. Waddell
Director, RA/QA
5 Musick
Irvine, California 92618

Re: K151536

Trade/Device Name: SmartTwist MRII Hand Drill, SmartTip MRII Drill Bit Kit, 4.5mm,
6.0mm

Regulation Number: 21 CFR 882.4300

Regulation Name: Manual cranial drills, burrs, trephines, and their accessories

Regulatory Class: Class II

Product Code: HBG

Dated: June 6, 2015

Received: June 8, 2015

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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
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)

K151536

Device Name

SmartTwist™ MRII Hand Drill, SmartTip™ MRII Drill Bit Kit, 4.5mm, 6.0mm

Indications for Use (*Describe*)

The SmartTwist™ MRII Hand Drill and accessories are 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 strength. The SmartTwist MRII Hand Drill and accessories are intended to be used only when the scanner is not performing a scan. The SmartTwist MRII Hand Drill is intended for single use only.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)
Subpart C)

Over-The-Counter Use (21 CFR 801)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

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

1. Company Making the Submission:

Name of Owner:	MRI Interventions, Inc.
Address:	5 Musick Irvine, CA 92618
Telephone:	949-900-6833, 949-584-8517
Fax:	949-900-6834
Contact:	Edward Waddell
E-mail:	ewaddell@mriinterventions.com

2. **Date Prepared:** July 8, 2015

3. Device Name:

Common Name:	Manual Drill
Proprietary Name:	SmartTwist MRII Hand Drill, SmartTip™ MRII Drill Bit Kit, 4.5mm, 6.0mm
Classification:	II
Regulation Number:	21CFR 882.4300
Product Code:	HBG

3. Predicate Device:

MRII Cranial Drill, K122456

4. Device Description:

The SmartTwist MRII Hand Drill is a hand held manual drill with a 3:1 gear ration. It is intended for use with the drill kit accessory kits SmartTip Drill Kits for a 3.2mm, 4.5mm and 6.0mm drill bit, with lancet, depth stop and ruler.

5. Indications for Use

The SmartTwist MRII Hand Drill and accessories are 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 strength. The SmartTwist MRII Hand Drill and accessories are intended to be used only when the scanner is not performing a scan. The SmartTwist MRII Hand Drill is intended for single use only.

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

Modifications of the predicate MR II Hand Drill are the additions of two additional drill kits.

- a) SmartTip Drill Bit Kit, 4.5-mm, with 4.5-mm Surgibit® Drill Bit, Drill Stop, Ruler, and Lancet
- b) SmartTip Drill Bit Kit, 6-mm, with 6-mm Surgibit® Drill Bit, Drill Stop, Ruler, and Lancet

	MR II Hand Drill and Accessories 4.5 & 6.0mm Drill Kits	Predicate Device MR II Cranial Drill and Accessories K122456
Classification	21 CFR 882.4300	21 CFR 882.4300
Product Code	HBG	HBG
Intended Use	The SmartTwist MR II Hand Drill and accessories are 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 strength. The SmartTwist MR II Hand Drill and accessories are intended to be used only when the scanner is not performing a scan. The SmartTwist MR II Hand Drill is intended for single use only.	The MR II Cranial Drill and accessories are 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 strength. The MR II Cranial Drill and accessories are intended to be used only when the scanner is not performing a scan. The MR II Cranial Drill is intended for single use only.
Environment	OR or MRI Suite	OR or MRI Suite
Sterilization	EO 10 ⁻⁶ SAL	EO 10 ⁻⁶ SAL
Drill Bit Included with Drill	No	No
Drill Bit Sizes	4.5mm 6.0mm	2.0mm 3.2mm
Drill Bit Material	316L SST	316L SST
Adjustable Depth Guard	Yes	Yes

Packaging	Kit: Sterile, inside tray with Tyvek Lid and external Tyvek Pouch	Drill: Sterile, CSR Wrap in Tyvek Peel Pouch Kit: Sterile, inside tray with Tyvek Lid and external Tyvek Pouch
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The addition of drill sizes is at the request of clinicians.

The addition of two drill kit sizes as accessories to the SmartTwist MR II Hand Drill is equivalent in intended use, technological characteristics and principles of operation to the predicate MR II Cranial Drill.

7. Performance Data:

The modifications of the SmartTwist MR II Hand Drill were conducted in conformance with the company’s design control procedures. Design inputs provided the requirements for the respective product specifications. Design Verification was performed relative to these specifications with acceptable results. Risk analysis was performed with mitigation of all identified risks to acceptable levels. The tests and risk analysis demonstrated that the modified SmartTwist MR II Hand Drill functions as intended and performs comparably to the legally marketed MR II Cranial Drill.

8. Consensus Standards:

The SmartTip MR II Drill Kits comply with the following recognized consensus standards:

- AAMI/ANSI/ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing.
- ANSI/AAMI/ISO 1135-1 Sterilization of health care - products - Ethylene oxide - Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices
- ASTM F2052-05e1, Standard Test method for Measurement of Magnetically Induced Displacement Force on Medical Devices in an MRI Environment.

9. Conclusion:

The modifications to the SmartTwist MR II Hand Drill were made in conformance with the company’s design control procedures. Performance testing established the equivalence of the modified SmartTip Drill Kits to the predicate SmartTwist MR II Hand Drill and accessories, including design verification testing. No new materials have been introduced so the safety testing with the MRI Cranial Drill Kits is fully applicable to the modified SmartTwist MR II Hand Drill and accessories.

The SmartTwist MRII Hand Drill has the same intended use and indications for use and similar technologies characteristics and principles of operation as the predicate MRII Cranial Drill. The minor technological differences between the SmartTwist MRII Hand Drill and accessories and its predicate raise no new issues of safety and effectiveness. Thus the modified SmartTwist MRII Hand Drill including the SmartTip Drill bit Kits 4.5mm and 6.0mm perform comparably to the predicate device that is currently marketed for the same intended use.