DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 26, 2016

MRI Interventions, Inc.
Mr. Peter Piferi
Chief Operating Officer
5 Musick
Irvine, California 92618

Re: K160129
Trade/Device Name: MRII Cranial Drill and Accessories
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 25, 2016
Received: February 25, 2016

Dear Mr. Peter Piferi:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160129

Device Name
MRII Cranial Drill and Accessories

Indications for Use *(Describe)*
The MRII 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 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.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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:	**Peter Piferi**
E-mail:	**ppiferi@mriinterventions.com**

2. Date Prepared:

January 12th, 2016

3. Device Name:

Common Name:	Manual Drill
Proprietary Name:	MRII Cranial Drill and Accessories
Classification:	II
Regulation Number:	21CFR 882.4300
Product Code:	HBG

4. Predicate Device:

MRII Cranial Drill and Accessories, K122456
SmartTwist MRII Hand Drill, SmartTip MRII Drill Bit Kit, 4.5mm, 6.0mm, K151536

5. Device Description:

The MRII Cranial Drill and accessories is composed of the MR Compatible Hand Drill and Drill Bit Kits, packaged separately and found substantially equivalent in K122456. The packaging is identical to that of the predicate device. The MRII Cranial Drill is wrapped in CSR and then sealed in a Tyvek pouch. The Drill Bit Kits are packaged in a sealed tray within a sealed Tyvek pouch.

6. Indications for Use

The MRII 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 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.

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

Modifications of the predicate MRII Cranial Drill and accessories are:
a) Changing the drill shaft material from PEEK to anodized aluminum
b) Changing the drill chuck housing material from PEEK to Delrin and adding a locking pin and slot
c) Shortening the slots on the chuck insert
d) Adding a shoulder feature to the drill chuck housing
e) Changing the shaft coupler material from PEEK to Delrin and adding a shoulder feature
f) Adding a lock washer to the back of the chuck housing
g) Adding a PTFE spacer between the pinion gear and drill housing
h) Modifying the proximal end of the 3.2-mm Drill Bit from a round shank with one flat to a round shank with three flats. This is an identical design that was reviewed and cleared under K151536.

The MRII Cranial Drill and 3.2mm Drill Bit shank modifications are part of continuous product improvement efforts. These minor changes make insertion of the Drill Bits and tightening of the Drill Chuck easier. These modifications will also allow the drill to rotate smoother with less run out.

	MRII Hand Drill and Accessories with minor design modifications	**Predicate Device MRII Hand Drill and Accessories K151536**
Classification	21 CFR 882.4300	21 CFR 882.4300
Product Code	HBG	HBG
Intended Use	The MRII 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 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 MRII 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 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
Environment	OR or MRI Suite	OR or MRI Suite

Sterilization	EO 10^{-6} SAL	EO 10^{-6} SAL
Hand Drill Shaft (non patient contacting, minor change to reduce run out, performs same function)	O.D: .245 in Length: 3.97 in Material: Anodized Al 6061	O.D: .240 in Length: 3.80 in Material: PEEK
Washer (non patient contacting, minor change to capture shaft coupler)	I.D: .435 in O.D: .625 in Thickness: .031 in Material: Nylon	N/A
Gear Housing Inner Lip Depth (minor dimension change to reduce play)	.060 in	.090 in
Dowel Pin (non patient contacting, minor change to prevent slipping)	O.D: .063 in Length: .313 in Material: 316 SS	N/A
Chuck Insert (minor dimension change to improve drill bit engagement)	Tri-Slot Length: .525 in Cross Pin Hole Dia: .063 in	Tri-Slot Length: .820 in Cross Pin Hole Dia: N/A
Drill Shaft Coupler (non patient contacting, minor dimensional changes and to accept pin and washer)	O.D: .468 in Length: 1.12 in Cross Pin Slot; Dia: .078 in, Length: .273 Lock Washer Step; Dia: .425 in, Length .506 in Drill Shaft Pilot Hole; Dia: .246 in, Depth: .225 in Material: Delrin	O.D: .500 in Length: .90 in Cross Pin Slot; N/A Lock Washer Step; N/A Drill Shaft Pilot Hole; N/A Material: PEEK
Drill Chuck Housing (non patient contacting, minor dimensional changes to improve assembly, accept washer and improve ergonomics)	Length: 1.57 in Lock Washer Seat; Dia: .642 in, Depth: .040 Shaft Coupler Pilot Hole; Dia: .469 in, Depth .66 in Material: Delrin	Length: 1.16 in Lock Washer Seat: N/A Shaft Coupler Pilot Hole: Dia: .547 in, Depth .25 in Material: PEEK
Shim (minor change to reduce play and friction)	I.D: .25 in O.D: .375 in Thickness: .030 in Material: Teflon	N/A
Drill Bit Included with Drill	No	No

Drill Bit Sizes (proximal shank feature, minor change to improve engagement)	3.2 mm (Tri Flat) 4.5 mm (Tri Flat) 6.0 mm (Tri Flat)	3.2 mm (Single Flat) 4.5 mm (Tri Flat) 6.0 mm (Tri Flat)
Drill Bit Material	316L SST	316L SST
Adjustable Depth Guard	Yes	Yes
Packaging	Drill: Sterile, CSR Wrap in Tyvek Peel Pouch 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

The modifications to the MRII Cranial drill and 3.2mm Drill Kit is substantially equivalent in intended use, technological characteristics and principles of operation to the predicate MRII Cranial Drill. Thus, the MRII Cranial Drill and 3.2mm Drill Kit modifications are substantially equivalent to the predicate.

8. Performance Data:

The modifications of the MRII Cranial Drill and 3.2mm Drill Kit 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 MRII Cranial Drill and 3.2mm Drill Kit functions as intended and is substantially equivalent to the legally marketed MRII Cranial Drill and accessories.

Verification Testing Performance Summary
Modified MRI Hand Drill (K160129) Compared to the Predicate MRI Hand Drill (K122456, K151536)
Testing per VPR-0111 Rev A.

Test	Test Method Summary	Results
Drilling Efficiency, Smooth Operation, and Vibration during Drilling	**Purpose**: To evaluate the Drilling Efficiency, smooth operation, and vibration during drilling, of the MRI Hand Drill. **Set-up**: A block of sawbones with a hardness of 65D was used as the simulated skull material. Simulated scalp material was placed on top of	All modified MRI Hand Drills met the acceptance criteria. All Hand Drills were able to drill through the simulated material in under a minute and received user evaluation scores greater than 3.0 for both smooth operation and vibration during drilling. This was substantially equivalent to the predicate

	the Sawbones block. The sample was clamped with a table vice, and placed on a weight scale. The Hand Drills were used to drill holes through the simulation material, using a drill speed of 1 handle turn per second, for each trial. 3.2, 4.5, and 6.0 mm Drill bits were used with each Hand Drill Tested. **Acceptance Criteria:** Drilling Efficiency: Drill through simulated material in under 1 minute. Smooth Operation and Vibration During Drilling: User evaluation score of 3.0 (scale of 1.0 – 5.0) or higher.	Hand Drill.
Drill Bit Retention under Axial Loading, Drill Bit Loading, and Handling with Wet Gloves	**Purpose**: To determine how well the Hand Drills' Chuck grips the Drill Bit, when an axial loading is applied to the Drill Bit. **Set-up**: A Drill Bit was attached to the MRI Hand Drills, using wet gloves; The Drill Bit was not fully seated inside the Chuck, to allow for it to slip in compression. Then, the Drill was clamped to the table, using a table vice and clamping directly on the Drill, such that the Drill Bit hangs freely. A Force Gauge was then attached to the Drill Bit, to administer a 5.0 lbf minimum compression load, and see if Drill Bit would slip further into the Chuck. Afterwards, The Force Gauge was used to pull on the Drill Bit, to administer a 5.0 lbf minimum force, and see if the Drill Bit would slip out of the	All modified MRI Hand Drills met the acceptance criteria. None of the modified Hand Drills had any slippage when a minimum axial load of 5.0 lbf was applied in both tension and compression directions. The Drill Bit Loading and Wet Glove usage requirements both scored higher than 3.0 for all modified Hand Drills tested. This was substantially equivalent to the predicate Hand Drill.

	Chuck in tension. Marks were made on the drill bits to measure the slippage based on the before and after measurements. This test was performed for the 3.2 and 4.5 mm Drill Bits with the Tri-flat geometry. **Acceptance Criteria**: Drill Bit Retention Under Axial Loading: 0 mm slippage under a 5.0 lbf minimum force. Drill Bit Loading, Wet Glove Usage: a user evaluation score of 3.0 (scale of 1.0 – 5.0) or higher.	
Drill Bit Retention under Torque Loading, Drill Bit Loading, and Handling with Wet Gloves	**Purpose**: To determine how well the Hand Drills' Chuck grips the Drill Bit, when Torque is applied to the Drill Bit. **Set-up**: A Drill Bit was attached to each MRI Hand Drill, using wet gloves. Then, the Drills were clamped to the table, using a table vice. A Torque Gauge was attached to the opposite end of the drill bit. A Torque was then applied to the drill, to see if there was any noticeable slip. Alignment marks where made of the Drill Bit and Chuck Housing, to see if there was any misalignment after applying the torque. This test was performed for the 3.2 and the 4.5 mm Drill Bits with Tri-flat geometry. **Acceptance Criteria**: Drill Bit Retention Under Torque: No movement of the Drill Bit inside the Chuck Housing,	All modified MRI Hand Drills met the acceptance criteria. None of the modified Hand Drills had any slippage when a minimum torque 10 in-lbf was applied to the Drill Bits. The Drill Bit Loading and Wet Glove usage requirements both scored higher than 3.0 for all modified Hand Drills tested. This was substantially equivalent to the predicate Hand Drill.

	when a Torque is applied to the Drill Bit. Drill Bit Loading, Wet Glove Usage: a user evaluation score of 3.0 (scale of 1.0 – 5.0) or higher.	
MRI Hand Drill and Drill Bit Run-out Testing (new comparative test)	**Purpose**: To measure the amount of Run-out in the Hand Drill/Drill Bit assembly, when the drill is rotating. **Set-up**: The Hand Drill Body was clamped in a table vice, such that the Hand Drill could still spin freely. A Drill Bit was attached to the Drill. A deflection gauge was placed at different point on the drill; on the Shaft Coupler, The Chuck Housing, on the Drill Bit near the Chuck Housing. The Drills were then turned, to see how much "wobble" was measured at each point. This was repeated for **Acceptance Criteria**: The modified Hand Drill shows a reduction in the amount of Run out in the Drill and Drill Bit.	All modified Hand Drills had approximately a 50% reduction in the amount of run-out (unwanted movement). This improvement does not change the use, safety or effectiveness of the Hand Drill.
MRI Hand Drill Shaft Deflection Test (new comparative test)	**Purpose**: To measure the amount of deflection in the Shaft, when a side load is applied to the Chuck Housing. **Set-up**: The hand Drill Body is clamped into a table vice. A force gauge is used to apply a 5 lbf side loading onto the Chuck Housing. The amount of deflection of the Housing is measured with a deflection gauge.	All modified MRI Hand Drills had a reduction in the amount of deflection by approximately 60%, compared to the PEEK shafts of the predicate Hand Drill. This improvement does not change the use, safety or effectiveness of the Hand Drill.

	Acceptance Criteria: The modified MRI Hand Drills show a reduction in the amount of deflection in the shaft when a side load is applied to the Chuck assembly.	
Chuck Housing Lock Washer Break Force Test (new test; this test was not performed on predicate devices, since predicates does not have this feature)	**Purpose**: To characterize the strength of the Loctite bond between the Chuck Housing and Lock Washer. **Set-up**: Chucks were loosened fully on Hand Drills. Drill Bodies were clamped to a Table Vice. A clamp was attached to the Chuck Housing, which was connected to the Force Gauge. The Force gauge was used to pull on the Chuck Housing axially, until the bond between the Lock Washer and Chuck Housing broke. The break force was then measured. **Acceptance Criteria:** The Lock Washers shall have a minimum break force of 5 lbf.	All modified Hand Drills had a Lock Washer break force greater than 5.0 lbf. Predicate Hand Drills have not undergone this test, since they do not have a Lock Washer feature. This modification does not change the use, safety or effectiveness of the Hand Drill.
Chuck Tightening Torque vs. Chuck Insert Slip Torque (new comparative test developed when the New Pinned Chuck Insert design was introduced)	**Purpose**: The Chuck Insert's slip torque was measured at different tightening torques of the Chuck Housing. This was done to see how well the new cross pin feature inside the Insert prevents the Chuck Insert from spinning inside the Chuck Housing. **Set-up**: Each Chuck/Shaft sub-assembly was removed from each Hand Drill Gear Housing. A Drill Bit was	The modified Hand Drill design did not slip at any level of Chuck tightening torque. The predicate Hand Drill Chuck Insert slip torque is approximately equal to the Chuck Housing's tightening torque. The user no longer has to tighten the chuck on the modified Hand Drill beyond what it takes to hold the drill bit. This modification does not change the use, safety or

	inserted into the Chuck Housing, and the Chuck was tightened to a specific tightening torque, using a torque gauge. A separate torque gauge was attached to the drill bit, and was used to turn the drill bit until the Chuck Insert slips. The maximum slip torque was measured. This test was repeated at different levels of Chuck Housing tightening torque. **Acceptance Criteria**: The Chuck Inserts withstand a minimum torque of 5.0 in-lbf without slipping.	effectiveness of the Hand Drill.

Summary of Risk Analysis

An FMEA was performed for the Hand Drill with modifications (FMEA-0063).

The summary of the risk analysis is provided below. The following table is used for the O,S, and D rankings.

Occurrence (probability)	**Detection (Chance of detecting failure)**	**Severity (Clinical Effect)**	**Non-Hazardous Severity**
1 - Low (1 in 400)	1 – Detection is certain	1 – Unnoticeable to user. No effect on performance.	1 - No noticeable delay/ no dissatisfaction
3 - Infrequent (1 in 200)	2 – High probability of detection	3 – Minor impact to patient. Minimal impact to patient baseline status	3 - Minor delay/ slight dissatisfaction
5 - Periodic (1 in 100)	4 – Detection probability is moderate	5 – Patient injury not requiring treatment. Alteration of patient's clinical baseline status	5 - Noticeable delay/ statement of dissatisfaction likely
7 - High (1 in 50)	6 – Detection probability is low	7 – Reversible patient injury. Alteration of patient's clinical baseline status requiring treatment	7 - Prolonged delay/ dissatisfaction communicated clearly
10 - Very High (1 in 25)	8 – Slight probability of detection	8 – Irreversible patient injury	8 - Extensive delay / extreme dissatisfaction

	10 – Detection almost impossible	10 – Death	10 - Procedure discontinued

There were no items with residual RPN above 40. The highest severities (9) were for susceptibility to magnetic force or torque, as that could cause either loss of control or could cause the MRI Drill to be pulled into the scanner at high speed. However, this occurrence is essentially zero because the Drill is designed with non-ferromagnetic components. There are two cross-pins that are made out of 316L Stainless Steel. 316L has very low magnetic susceptibility, and the mass of the stainless steel pins is insignificant compared to the overall mass of the Hand Drill. The same 316L SST Pin is used in the predicate Hand Drill. Therefore, this risk is identical to the predicate Hand Drill.

The modified MRI Drill Shaft is also made out of anodized 6061 Aluminum. This modification to the Hand Drill did not increase any of the RPN's from the risk analysis performed on the predicate device.
The aluminum shaft has extremely low magnetic susceptibility (much lower than 316L SST), so it is unaffected by magnetic fields from 1.5T – 3.0T. So, the risk remained the same as the predicate Hand Drill.

The only new failure mode was the lock washer breaking off from the Chuck Housing. However, this has no clinical effect, and the occurrence is 1. The lock washer provides a benefit to the user since it prevents the Chuck Housing from falling off when the user loosens it. So the benefit of having the washer far outweighs the very minimal risk.

The modified Hand Drill also lowers the occurrence of two failure modes.

The Collet Jaws deforming during tightening the Chuck is now 1 (predicate device was 2), which lowers the RPN from 8 to 4.

The Chuck Housing does not have a good gripping surface for User to tighten adequately is now 1 (predicate device was 3), which lowers the RPN from 24 to 8.

All material changes from the predicate device are non patient contacting and do not provide any additional risk. The modified Hand Drill poses no additional challenge to sterilization over the predicate Hand Drill and therefore does not pose any additional risk.

The modifications to the Hand Drill do not increase the risks from the predicate Hand Drill.

The MRI Hand Drill is a safe alternative to power drills. It is still the case that the device operates at very low speed, and is manually powered. Both of these characteristics lead to a safe device in most cases. Most of the failures of the device occur toward the safe end—that is, the device does not spin or stops being usable, instead of failures that result in a loss of control. There were no new failure modes uncovered during testing that challenge the premise. In addition, most of the failure modes associated with the device are considered non-hazardous, as they do not result in any harm to the patient. The drill allows users to create small holes for interventional procedures in the MRI scanner. This is a great benefit to surgeons and patients, as it makes procedures faster and logistically easier. Therefore, the benefits of the device outweigh the risks.

For the Drill Bit, there are also no new risks with the change to the shank geometry.

The Drill Bit had no material changes, so the highest severity items (FMEA-0064) remain unchanged:

Resistance Magnetic Force Displacement (RPN = 16, Severity = 8)
Drill made of non-biocompatible material (RPN = 80, Severity = 8)

The change to the shank geometry does not add any new risks. As testing showed, it will only improve performance and allow users to exert less force to tighten the drill bit in the drill without slipping.

9. Consensus Standards:

The MRII Cranial Drill and accessories 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 Devcies in an MRI Environment.

10. Conclusion:

The modifications to the MRII Cranial Drill and 3.2mm Drill Kit were made in conformance with the company's design control procedures. Performance testing established the substantial equivalence of the modified MRII Cranial Drill and 3.2mm Drill Kit to the predicate MRII Cranial Drill and accessories, including design verification testing.

The MRII Cranial Drill has the same intended use and indications for use and similar technologies characteristics and principles of operation as the predicate Cranial Drill. The minor technological differences between the MRII Cranial Drill and accessories and its predicate raise no new issues of safety and effectiveness. Thus the modifications are substantially equivalent to the previously cleared MRII Cranial Drill and accessories.