**510(k) Summary**

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the MRII MR Compatible Ventricular Catheter.

1. **Company Making the Submission:**

AUG 1 6 2013

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

2. **Device Name:**

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|---|---|
| Common Name: | Ventricular Catheter |
| Proprietary Name: | MR Compatible<br>Ventricular Catheter |
| Classification: | Class II |
| Regulation Number: | 882.4100 |
| Product Code: | HCA |

3. **Predicate Device:**
MRII Ventricular Cannula, K102101

4. **Intended Use Statement:**
The SmartFlow™ Flex Ventricular Catheter is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."

5. **Description of Device:**

The Catheter has a stepped distal tip with a 30 cm removable rigid ceramic stylet protecting the fluid lumen while providing rigidity to the distal portion of the device. The stylet is removed after insertion to the desired point. Soft tubing protects the lumen in the center portion and at the distal end where it terminates. The fluid containing central lumen is manufactured from PEEK tubing.

The Catheter will be marketed in the following sizes:

Ventricular Catheter .008 x 7.5mm tip
Ventricular Catheter .008 x 15mm tip
Ventricular Catheter .021 x 7.5mm tip
Ventricular Catheter .021 x 15mm tip

Each unit will provide for an approximate 23 inch tubing extension.

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

| | MRII Ventricular Catheter | Predicate Device: MRII Ventricular Cannula | Discussion |
|---|---|---|---|
| **Classification** | 21 CFR 882.4100 | 21 CFR 882.4060 | Equivalent |
| **Product Code** | HCA | HCD | Equivalent |
| **Premarket Notification** | TBD | K102101 | Equivalent |
| **Intended Use** | The SmartFlow™ Flex Ventricular Catheter is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only." | The MR Compatible Ventricual Cannula is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. The device is intended for "single patient use only" | Equivalent |
| **Target Population** | Any Pt's needing aspiration or injection of fluids from the brain ventricles | Any Pt's needing aspiration or injection of fluids from the brain ventricles | Equivalent |
| **Anatomical Sites** | Brain ventricle | Brain ventricle | Equivalent |
| **Where Used** | OR or MRI suite | OR or MRI Suite | Equivalent |
| **Energy used** | N/A | N/A | N/A |
| **Human Factors** | Labeling indicates size and length | Labeling indicates size and length | Equivalent |
| | Can be manipulated with gloved hand | Can be manipulated with gloved hand | Equivalent |
| **Design** | Designed to be placed through a prepared opening through the skull and dura into the brain ventricle | Designed to be placed through a prepared opening through the skull and dura into the brain ventricle | Equivalent |
| | Rigid and straight section to enter the brain, rigid section can be removed after insertion | Rigid and straight section to enter the brain | Equivalent, except the rigid section can be removed after insertion of the catheter |

| | MRII Ventricular Catheter | Predicate Device: MRII Ventricular Cannula | Discussion |
|---|---|---|---|
| | Hole at distal end for fluid movement | Hole at distal end for fluid movement | Equivalent |
| | Length of rigid section: 10.5" (30 cm) | Length of rigid section: 10.5" (30 cm) | Equivalent |
| | Tip design identical to that of the Ventricular Cannula | Tip design as described in K102101 | Equivalent |
| | Sufficiently rigid to pass through brain tissue without additional support | Sufficiently rigid to pass through brain tissue without additional support | Equivalent |
| | Contains a channel through which fluids can be removed (aspiration) or placed (injection) into the ventricle | Contains a channel through which fluids can be removed (aspiration) or placed (injection) into the ventricle | Equivalent. Flow rates are higher for the catheter due to the shorter tubing length. |
| | Flow rate of: 4.0 ml/hr (.008" I.D.) to 56 ml/hr (.021" I.D.) at 0.7 PSI | Flow rate of: 0.6 ml/hr (.008" I.D.) to 34 ml/hr (.021" I.D.) at 0.7 PSI | |
| | Rigid body: Ceramic | Rigid body: Ceramic | Equivalent |
| | Through lumen PEEK | Through lumen: Polymer covered silica | Equivalent, both meet biocompatibility requirements |
| **Materials** | MRI Safe | MRI Safe | Equivalent |
| | Proximal Connector: Female Luer adapter connector, external to kit as described in IFU | Proximal Connector: Female Luer connector | Equivalent, both can be connected to a syringe. Catheter requires a user supplied common component to make the connection. |
| **Biocompatibility** | Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices | Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices | Equivalent |
| **Cytotoxicity** | Acceptable | Acceptable | Equivalent |
| **Systemic Toxicity, SC & SO extracts** | Acceptable | Acceptable | Equivalent |
| **Pyrogen Material Mediated** | Acceptable | Acceptable | Equivalent |
| **Intracutaneous Study, SC & SO extracts** | Acceptable | Acceptable | Equivalent |

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| **ISO Maximization SC & SO extracts** | Acceptable | Acceptable | Equivalent |
| **Sterility** | Yes per ANSI/AAMI/ISO 11137-2: Sterilization of health care products -- Radiation | Yes per ANSI/AAMI/ISO 11137-2: Sterilization of health care products -- Radiation | Equivalent |
| **Electrical Safety** | N/A | N/A | Equivalent |

**7. Summary of difference from the predicate**

The MRII ventricular catheter differs from that of the cannula in four principal ways.

a) The fluid delivery tubing is composed of PEEK rather than the silica of the predicate

b) The fluid delivery tubing is shorter (23 inch nominal) versus 4 and 10 feet of the predicate.

c) The MRII ventricular cannula provides for a bone anchor, for subsequent infusions over a period of 24 hours.

d) The rigid component of the catheter can be removed after insertion so that the catheter is flexible along its whole length. The cannula's rigid section is integrated into the assembly.

**8. Testing:**

Testing to applicable standards has been completed with acceptable outcomes. The following testing has been performed:

- Sterilization and Shelf Life
- Biocompatibility: Both the ventricular catheter and the bone anchor were tested under conditions of Good Laboratory Practices in the following tests with acceptable results.

| Study | Result | Conclusion |
|---|---|---|
| Cytotoxicity Study, MEM Elution | "The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade of 2 (mild reactivity)." | Non-cytotoxic |
| ISO Systemic Toxicity, SC and SO Extracts | "There was no mortality or evidence of systemic toxicity from the extracts. The test article extracts met the requirements of the study." | Non-toxic |

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| Pyrogen Study – Material Mediated | "The total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP limits. The test article was judged as nonpyrogenic." | Non-pyrogenic |
| ISO Intracutaneous Study, SC and SO Extracts | "The test article met the requirements of the test since the difference between each test extract overall mean score and corresponding control overall mean score was 0.0 and 0.2 (0.4 bone anchor) for the SC and SO test extracts, respectively." | No significant erythema or edema |
| ISO Maximization Sensitization Study, SC and SO Extracts | "The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test." | Non-sensitizer |
| Drug/Device Compatibility Testing | HPLC using USP Monograph assay for cytarabine concentration | No leaching of materials or uptake of cytarabine |

- Performance Testing – Bench

| Test | Methodology | Conclusions |
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| Flow Rate Testing | Set flow rate on infusion pump to specification rate. Measure amount of fluid collected over a set period of time. Measure pressure for reference. | Specified flow rates of 0.5 mL/hr and 0.3 mL/hr were achieved with the infusion pump. |
| Flow Rate Testing, constant pressure | Set flow rate on infusion pump so that measured pressure is 0.7 psi. Measure amount of fluid collected over a set period of time. | Flow rates at 0.7 psi for the device were greater than the predicate as expected.<br><br>.008" ID Predicate 0.6 mL/hr<br>.008" ID Device 4.0 mL/hr<br><br>.021" ID Predicate 34 mL/hr<br>.021" ID Device 56 mL/hr |

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| High Pressure Flow Testing | Use hand held syringe to apply very high pressure via hand force. Measure amount of fluid collected over a set period of time. | High pressure flow is equivalent to or better than the predicate. The main difference comes from the shorter tubing length of the device and different applied pressure since hand force was used. |
| Aspiration | Use hand held syringe and apply vacuum to fixed amount of fluid. Record time to aspirate fluid. | Results were better than (higher aspiration rates achievable) the predicate. The main difference comes from the shorter tubing length of the device. |
| Leak/Burst Testing | Block the cannula tip. Use a hand held syringe or manual pump to apply 70 psi minimum pressure to the Catheter. Watch for leaks anywhere along the length. | Results were equivalent to the predicate device. The 70 psi specification is the same. All samples withstood 70 psi internal pressure without any leaks. |
| Distal Tip Compressive Strength | Apply axial compressive load to distal tip on 50A durometer material. Examine tip under magnification to check for damage. | Results were equivalent to the predicate, which has the same specification. All samples met the requirement without damage to the tip. |
| Distal Tip Lateral Load | Apply side load to distal tip section to a minimum force limit. | Results were substantially equivalent to the predicate, which had the same specification. All samples met the specification. |
| Ceramic Stylet Lateral Load | Hold Catheter with Stylet approximately 6 cm from the distal end (5 cm from the applied load). Apply lateral load and measure force to breakage. | Device met the specification, which is the same specification as the predicate. Predicate device has a fixed integrated rigid tube, not a removable internal stylet. |
| Catheter Axial Tensile Load | Apply a tensile load to the catheter. Pull to failure. Catheter is held at the outer capillary and at the PEEK tubing. Catheter was then held at the outer capillary and the Pebax tubing. | Results were equivalent to the predicate. The specification is the same as the predicate. All devices met the specification. |
| Catheter Insertion into Bone Anchor | Insert the device into the bone anchor. Observe for any interference or difficulty. | The device was inserted into the Bone Anchor without difficulty. |
| Catheter Retention in Bone Anchor | Apply pull force to the specified limit to determine if | All samples were retained to the specification. |

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| | the Catheter remains in place in the Bone Anchor | |
| Stylet Removal from Bone Anchor | Once the catheter is tightened in the Bone Anchor, measure the pull force required to remove the Stylet from the Catheter. | The device met the specification of maximum pull force for Stylet removal.<br><br>The predicate device has an integrated ceramic tube and does not have removable Stylet. |
| Catheter Tissue Insertion | Pass the device through bovine brain tissue to a 4 inch depth. Extract the device and check for plugging or damage. | Equivalent to the predicate device. There was no tissue in or on the device after insertion and removal. |
| Backflow | Insert the device into brain-simulating gel. Use an infusion pump at a set flow rate to drive dyed fluid through the device. Examine the gel for any dye that runs back up the sides of the device. | Equivalent to predicate device. There was no observed backflow. |
| Tip Deflection at Max Pressure | Plug a catheter tip. Mark the position of the tip. Apply 70 psi internal pressure to the catheter. Mark the position of the tip with pressure applied. Determine the difference (if any) between the marks. | Equivalent to the predicate device. There was no movement of the tip at applied internal pressure of 70 psi. |
| Tip Deflection at Max Aspiration | Plug a catheter tip. Mark the position of the tip. Apply 2 psi vacuum to the catheter. Mark the position of the tip with pressure applied. Determine the difference (if any) between the marks. | Equivalent to the predicate device. There was no movement of the tip at applied vacuum of 2.0 psi. |
| Bend Radius Withstand | Wrap the device tubing for ½ turn around a specified diameter rod. Examine the tubing for kinks or other damage. | Equivalent to the predicate device. There was no kinking or damage to the tubing at the specified bend radius. |
| Syringe Dropping Test | Connect the device to a syringe. Drop the syringe with the device anchored in place. After the syringe drop, check the device for damage and operation. | Equivalent to the predicate device. There was no damage sustained by the device after the syringe was dropped with the device connected. |

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| Tip Deflection after Stylet Removal | Insert Catheter with Stylet into brain simulating gel in a clear beaker. Mark the spot on the beaker where the tip touches. Lock the catheter in place. Remove the Stylet and observe for tip deflection away from the mark. | There was no tip movement upon Stylet removal. Device met specification. |
| Bone Anchor Insertion Force | Insert Bone Anchor into drilled hole and measure the amount of downward force required from beginning to end of insertion. | All Bone Anchors were all inserted fully with a downward force below the requirement. |
| Bone Anchor Insertion Torque | Insert Bone Anchor into drilled hole and measure the amount of torque required from beginning to end of insertion. | All Bone Anchors were all inserted fully with a torque below the requirement. |
| Bone Anchor Side Load Force | Insert a Bone Anchor into a drilled hole. Apply a side load to the minimum specified level to four points around the bone anchor diameter. Inspect for damage or yielding. | All Bone Anchors all withstood the minimum load with no damage or yielding. |
| Bone Anchor Side Impact Force | Insert a Bone Anchor into a drilled hole. Apply a lateral impact load on four different points around the bone anchor diameter by dropping a known weight from a specified height to obtain an applied energy. Inspect for damage or yielding. | All Bone Anchors withstood the minimum energy without damage or yielding. |
| Bone Anchor Retention Force | Insert a Bone Anchor into a drilled hole. Tighten a catheter into the Bone Anchor and apply a tensile load to the catheter to the minimum specified limit. | All Bone Anchors remained in place under the applied tensile load. |
| Bone Anchor-Driver Detachment Force | Insert a Bone Anchor into a drilled hole using the Driver. Measure the tensile force required to remove the Driver from the Bone Anchor. | All pairs of Bone Anchors and Drivers were below the maximum limit for detachment force. |

Bench testing included design verification testing and comparison testing with the predicate MRII Cannula, demonstrating the MR Compatible Ventricular Catheter functions as intended and is substantially equivalent to the legally marketed device.

**9. Rx or OTC:**

The MR Compatible Ventricular Catheter is an Rx prescription device per 21 CFR Part 801, Subpart D.

**10. Substantial Equivalence:**

The MR Compatible Ventricular Catheter is as safe and effective as the predicate MRII Cannula. The MR Compatible Ventricular Catheter has the same intended uses and identical indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the MR Compatible Ventricular Catheter and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the MR Compatible Ventricular Catheter is as safe and effective as the MRII Cannula. Thus the MR Compatible Ventricular Catheter is substantially equivalent.

MRII, Inc.

E. F. Waddell
Director of Regulatory Affairs

Date: 8/16/13

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

August 16, 2013

MRI Intervention Inc.
Edward Waddell
5 Musick
Irvine, CA 92618

Re: K123605
Trade/Device Name: SmartFlow Flex Ventricular Catheter
Regulation Number: 21 CFR 882.4100
Regulation Name: Catheter, Ventricular
Regulatory Class: Class II
Product Code: HCA
Dated: July 16, 2013
Received: July 17, 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 contact 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. 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 -S

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: **K123605**

Device Name: MRI Intervention, Inc. SmartFlow™ Flex Ventricular Catheter

Indications For Use:

The SmartFlow™ Flex Ventricular Catheter is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

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

510(k) Number K123605