July 13, 2018

IRRAS Inc.
Dessi Lyakov
Director, Regulatory Affairs and Quality Assurance
7452 Herschel Avenue
La Jolla, California 92037

Re: K171880
Trade/Device Name: IRRAflow CNS System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG, GWM
Dated: June 11, 2018
Received: June 13, 2018

Dear Dessi Lyakov:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng
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for 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171880

Device Name
IRRAflow CNS System

Indications for Use *(Describe)*
The use of IRRAflow CNS System is indicated when intracranial pressure monitoring is required and for externally draining intracranial fluid as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed for ≤ 24 hours.

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.**

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

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# 510(k) Summary – K171880


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Date prepared: July 11, 2018

Trade name: IRRAflow® CNS System
Common Name: CSF Drainage System with ventricular catheter

Primary Classification:
Name: Central Nervous System Fluid Shunt and Components
Product Code: JXG
Regulation: 21 CFR 882.5550

Secondary Classification:
Name: Intracranial Pressure Monitoring Device
Product Code: GWM
Regulation: 21 CFR 882.1620

Predicate and Reference Device(s):
K984053 Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS)
K160223 VentriClear II Ventricular Drainage Catheter

## DEVICE DESCRIPTION

The IRRAflow® CNS System is an intracranial pressure (ICP) monitoring and drainage system. The IRRAflow CNS System consists of an IRRAflow Control Unit and two sterile disposable parts, the IRRAflow Tube Set and the IRRAflow Catheter.

The drainage flow of cerebrospinal fluid (CSF) into the IRRAflow Catheter is uni-directional and gravity-driven; there is no recirculation of the CSF. A parallel line from the saline infusion bag is used in case clearance at the tip of the catheter is required. The IRRAflow Tube Set has a cassette that clicks on to the IRRAflow Control Unit and aligns the tubing against a peristaltic pump and pinch valve. An aspiration bag is attached to the Control Unit tape measure, defining the height of the bag relative to the catheter's tip position in the patient's head and thus controlling the speed of drainage. The tubing and catheter can be disconnected and connected by standard Luer-Lock connectors. Settings can be changed via the user interface on the Control Unit.

The default mode provides drainage and measuring ICP, allowing single bolus injections when indicated. The bolus injections allow the catheter to be flushed when it becomes clogged. CSF or intracranial fluid samples can be taken from the aspiration port.

## INDICATIONS FOR USE

The use of IRRAflow CNS System is indicated when intracranial pressure monitoring is required and for externally draining intracranial fluid as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed for ≤ 24 hours.

## SUBSTANTIAL EQUIVALENCE

The IRRAflow CNS system's intended use, technological characteristics and principles of operation are similar to the Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS) (K984053).

Comparison of these Monitoring Systems is provided in table 1 below.

**Table 1** – Substantial Equivalence Comparison of the Monitoring Systems

| Items | Predicate<br>Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS) (K984053)<br>(JXG), (GWM) | IRRAflow CNS System<br>(K171880)<br>(JXG), (GWM) | Equivalence |
|---|---|---|---|
| **Primary Product Code** | JXG | JXG | Same |
| **Primary Regulation Number:** | 21 CFR 882.5550 | 21 CFR 882.5550 | Same |
| **Secondary Product Code** | GWM | GWM | Same |
| **Secondary Regulation Number:** | 21 CFR 882.1620 | 21 CFR 882.1620 | Same |
| **Indications for Use** | Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:<br><br>Reduce intracranial pressure (ICP), e.g., pre, intra- or postoperative.<br>Monitor CSF chemistry, cytology, and physiology.<br>Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts. Monitoring of intracranial pressure (ICP) is indicated in selected patients with:<br>Severe head injury<br>Subarachnoid hemorrhage graded III, IV, or V preoperatively<br>Reye's syndrome or similar encephalopathies<br>Hydrocephalus Intracranial hemorrhage<br>Miscellaneous problems when drainage is to be used as a therapeutic maneuver<br><br>Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions. | The use of IRRAflow CNS System is indicated when intracranial pressure monitoring is required and for externally draining intracranial fluid as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed for ≤ 24 hours. | See discussion below |
| **Injection/ CSF Sampling Ports** | Yes | Yes | Same |
| **Unidirectional Flow of Drained Fluid** | Yes | Yes | Same |
| **Fluid Injection Capability** | Yes | Yes | Same |

| Items | Predicate<br>Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS) (K984053)<br>(JXG), (GWM) | IRRAflow CNS System<br>(K171880)<br>(JXG), (GWM) | Equivalence |
|---|---|---|---|
| **Attaches to separate, commercially available EVD Catheter** | Yes | Yes<br>The IRRAflow system attaches to IRRAflow Catheter which is an EVD Catheter part of the complete system. | Same<br>See discussion below |
| **Sterile Disposable tubing set** | Yes | Yes | Same |
| **CSF Drainage Bag** | Yes | Yes | Same |
| **Gravity drainage of CSF** | Yes | Yes | Same |
| **Method to control gravity drainage of CSF** | Manual adjustment of the drip chamber either up or down the IV Pole, relative to the patient's head position and ventricular catheter location. | Automated adjustment based on user settings via a stepper-motor controlled, tube-pinching mechanism to either compress or release the compliant drainage tubing contained within the sterile, disposable Cartridge. | See discussion below |
| **Pressure Transducer for ICP Measurement** | Yes<br><br>(The Duet System includes a design and instructions for attaching a transducer that allows for ICP measurement and visual display via a connected monitor.) | Yes<br><br>(The IRRAflow system integrates transducers into its design for measurement and visual display of ICP) | Same |
| **Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP Monitoring** | No | Yes | See discussion below |
| **Method to account for location of ventricles via patient head position** | Laser level must be attached to the system and leveled and then the system "zeroed"; adjustment thereafter may be needed. | Reference marks on the device to allow for the system to be aligned with patient's head positioning. | Equivalent<br>See discussion below |
| **Measured Pressure Range** | 0 – 31 cm H2O (set ICP range) | -80 mmHg to +100 mmHg | See discussion below |
| **Displayed ICP** | Yes<br>(via drip chamber pressure indicator window or via connected transducer to patient monitor display) | Yes | Equivalent |
| **Battery Back-up** | No (Manual, non-powered system) | Yes | See discussion below |

***Discussion of differences in Table 1***

**IFU:**

| Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS) (K984053) | IRRAflow CNS system (K171880) | Discussion: |
|---|---|---|
| **Indications for Use:** | | |
| Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:<br>• Reduce intracranial pressure (ICP), e.g., pre-, intra- or postoperative.<br>• Monitor CSF chemistry, cytology, and physiology.<br>• Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.<br>Monitoring of intracranial pressure (ICP) is indicated in selected patients with:<br>• Severe head injury<br>• Subarachnoid hemorrhage graded III, IV, or V preoperatively<br>• Reyes syndrome or similar encephalopathies<br>• Hydrocephalus<br>• Intracranial hemorrhage<br>• Miscellaneous problems when drainage is to be used as a therapeutic maneuver.<br>Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions. | The use of IRRAflow CNS System is indicated when intracranial pressure monitoring is required and for externally draining intracranial fluid as a means of reducing intracranial pressure in patients where an external drainage and monitoring system is needed for ≤ 24 hours. | The IRRAflow CNS system is not suitable for lumbar drain.<br><br>The indications both include monitoring of Intracranial Pressure and drainage of intracranial fluid as a means of reducing intracranial pressure.<br><br>Equivalent Indications. |

**EVD Catheter:**
Both systems attach to a separate commercially available EVD catheter. The IRRAflow CNS system user manual instructs the users to only use approved IRRAflow catheters, which are provided by IRRAS Inc.
This does not impact the functionality or intended use of the system as compared to its predicates.

**Method to control gravity drainage of CSF:**
The IRRAflow CNS System has built in functionality to control the drainage of CSF which is different than the predicate, which relies on manual methods. This minor difference does not impact the functionality or intended use of the system when compared to its predicate.

**Software-based, Powered Console:**
For the predicate, a transducer can be attached that allows for ICP measurement and visual display via a connected monitor to provide a display and user interface for ICP monitoring.

The IRRAflow CNS System has this functionality built into the central unit reducing the risk of faulty connections impacting the readings. This minor difference does not impact the functionality or intended use of the system as compared to its predicate.

**Method to account for location of ventricles via patient head position:**
Both systems have methods to account for the location of the ventricles via the patient head position. The predicate uses a laser to align with the patient. The IRRAflow CNS System uses zero-line markings on the unit itself to align with the patient's head position.

This minor difference does not impact the functionality or intended use of the system as compared to its predicate.

**Measured Pressure Range:**
The predicate range of 0 to 31 cm $H_20$ translates to 0 to 22.8 mmHg. The wider range of the IRRAflow CNS System (-80 to 100 mmHg) does not impact the functionality or intended use of the system as compared to its predicate. The purpose of the larger ICP range is to provide the physician a broader breadth of data and information during treatment.

Any differences between the IRRAflow CNS System and the predicate systems do not alter the substantial equivalence or intended use of the IRRAflow CNS System. The substantial equivalence of the IRRAflow CNS System as compared to the predicate devices has been demonstrated via bench testing.

**Battery Back-up:**
The IRRAflow CNS System is designed with a battery backup which is an improvement over the predicate device. This minor difference does not impact the functionality or intended use of the system as compared to its predicate.

Any differences between the IRRAflow CNS System and the predicate systems do not alter the substantial equivalence or intended use of the IRRAflow CNS System. The substantial equivalence of the IRRAflow CNS System as compared to the predicate device has been demonstrated via bench testing.

**SUBSTANTIAL EQUIVALENCE**
The IRRAflow CNS System's Catheter technological characteristics and principles of operation are similar to the VentriClear II Ventricular Drainage catheter (K160223).

Comparison of these Catheters is provided in table 2 below

**Table 2** – Substantial Equivalence Comparison – Catheters

| Items | Predicate Device VentriClear II Ventricular Drainage catheter (K160223) | IRRAflow CNS System Catheter (K171880) | Equivalence |
|---|---|---|---|
| **Target Population** | Any patient needing removal of intracranial fluids from the brain ventricles | Any patient needing removal of intracranial fluids from the brain ventricles | Same |
| **Anatomical Sites** | Brain ventricles | Brain ventricles | Same |
| **Implant Procedure** | Designed to be placed through a prepared opening through the skull and into the brain ventricle | Designed to be placed through a prepared opening through the skull and into the brain ventricle | Same |
| **Catheter Size** | 9Fr | 9Fr | Same |
| **Catheter Length** | 330mm | 400mm | See discussion below |
| **Catheter Sideports** | Yes | Yes | Same |
| **Catheter End-hole** | Closed | Closed | Same |
| **Catheter Depth Markers** | Yes | Yes | Same |
| **Catheter material** | Silicone | Silicone | Same |
| **Antimicrobial Agents** | Minocycline/Rifampin | None | See discussion below |
| **Catheter Tip** | Radiopaque | Radiopaque | Same |
| **Biocompatibility** | Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices | Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices | Similar |
| **Cytotoxicity** | Acceptable | Acceptable | Same |
| **Provided Sterile** | Yes | Yes | Same |
| **Packaging** | Tyvek/polyester pouch | Tyvek/polyester pouch | Same |
| **Shelf Life** | 2 years | 18 months | See discussion below |

***Discussion of differences in Table 2***

**Catheter Working Length:**
The working length of the VentriClear II Catheter is 330mm; the IRRAflow Catheter working length is 400 cm.

The difference in catheter working length is not significant and does not impact the functionality or intended use of the system as compared to its predicates. The working lengths of both the VentriClear II Catheter reference device and the IRRAflow Catheter are within the range of working lengths of ventricular drainage catheters.

This does not impact the functionality or intended use of the system as compared to its predicates.

**Antimicrobial Agents:**
The VentriClear II Catheter material includes antimicrobial agents (minocycline and rifampin). The IRRAflow Catheter material does not include any antimicrobial agents. The absence of antimicrobial agents in the IRRAflow Catheter does not impact the functionality or intended use of the Catheter.

This does not impact the functionality or intended use of the system as compared to its predicates.

**Shelf Life:**
The VentriClear II Catheter has a shelf life of 2 years, whereas the IRRAflow Catheter currently has a listed shelf life of 18 months. The current difference in catheter shelf life is not significant and does not impact the functionality or intended use of the system as compared to its predicates.

**Verification and Validation Documentation:**
The IRRAflow CNS System tests include verification and validation performance testing as well as externals standards testing to demonstrate no new safety and effectiveness issues are raised with this new device. Analyses demonstrate that system accuracy and performance are adequate for the established intended use. In conclusion, the IRRAflow CNS System is substantially equivalent to the predicate device.

Table 3 below, identifies the testing conducted on the IRRAflow CNS System to demonstrate substantial equivalence.

**Table 3** – IRRAflow CNS System Testing

| **Test** | **Test Method Summary** | **Results** |
|---|---|---|
| ***Biocompatibility Testing*** | | |
| Systemic Toxicity, Mediated Pyrogen | The purpose of the study is to determine if a saline extract of the test article causes a febrile response in rabbits. | **PASS** Clinical Observations: The test article were determined to be non-pyrogenic. |
| Acute Systemic Toxicity, Injection Test | The purpose of the test was to screen test article extracts for potential toxic effects as a result of a single-dose systemic injection in mice. | **PASS** Clinical Observations: None of the animals on study were observed with abnormal clinical signs indicative of toxicity during the test period. |
| Irritation/Intracutaneous Reactivity Test | The purpose of the test was to determine if any chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of rabbits. | **PASS** Clinical Observations: None of the animals on study showed abnormal clinical signs during the observation periods. |
| Indirect Hemolysis (Extract) Test | The test is designed to determine the hemolytic properties of a medical device/material. | **PASS** Clinical Observations: All test method acceptance criteria were met. |

| Test | Test Method Summary | Results |
|---|---|---|
| Cytotoxicity (MEM Elution) Test | The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. | **PASS** Clinical Observations: All test method acceptance criteria were met. |
| Sensitization Test | This test was designed to evaluate the allergenic potential or sensitizing capacity of a test article. | **PASS** Clinical Observations: None of the animals in the study showed abnormal clinical signs. |
| ***Bench and Electrical Testing*** | | |
| IRRAflow CNS System Verification | The purpose of this test is to document the results of the system verification testing and system regression verification testing. | **PASS** The system has been shown to comply with the documented requirements for the system. |
| IRRAflow CNS System Validation | The validation test procedures for the IRRAS IRRAflow CNS system were designed to ensure that the device complies with established requirements. | **PASS** The system has been shown to comply with the documented requirements for the system. |
| IRRAflow CNS System Static Analysis | The purpose of this test is to describe the process and results from the static analysis of the IRRAflow CNS system software. | **PASS** There were no errors encountered when the static analysis was conducted. |
| Basic Safety test | The following tests were conducted: Input Test; Heating Test; Leakage Current Test; Dielectric Voltage Test. | **PASS** Acceptance criteria has been met. |
| Electromagnetic Compatibility test | The objective of the testing is to determine compliance with IEC 60601-1-2:2014 Class B. | **PASS** Acceptance criteria has been met. |
| IRRAflow Catheter Performance Test | The purpose of this test is to describe the tensile test results for the IRRAS catheter. | **PASS** Acceptance criteria has been met. |
| IRRAflow Catheter Torsion and Shear Test | The purpose of this test is to describe the torsion and shear testing results for the IRRAS catheter. | **PASS** Acceptance criteria has been met. |
| IRRAflow Catheter Drainage Flow Test | The purpose of this test is to describe the drainage testing methods for the IRRAS catheter. | **PASS** Acceptance criteria has been met. |
| **Test** | **Test Method Summary** | **Results** |
| ***Shelf Life / Package Integrity Testing*** | | |
| Validation of sterile barrier | The purpose of this test is to describe the procedures for validating that the sterile barrier meets design and standards requirements. | **PASS** Acceptance criteria has been met. |
| Packaging Peel Test | The purpose of this test is to describe the roll packing seal testing results for the IRRAS catheter and tube set. | **PASS** Acceptance criteria has been met. |
| Aging Test | The purpose of this test is to describe the objective evidence that the IRRAS catheter and tube set meet the appropriate requirements for transportation and aging. | **PASS** Acceptance criteria has been met. |
| ***Sterilization Testing*** | | |
| Sterilization process for the IRRAflow Catheter and IRRAflow Tube Set | This study was conducted to validate the effectiveness of electron beam radiation of IRRAflow Catheter and Ethylene Oxide sterilization of IRRAflow Tube Set. | **PASS** Acceptance criteria has been met. |

**Substantially equivalent summary:**
Performance data demonstrate that the IRRAflow CNS System is substantially equivalent to the predicate devices.

**Conclusion:**
The IRRAflow CNS System is substantially equivalent to the predicate, the Medtronic PS Medical External Drainage and Monitoring System (Becker EDMS) (K984053) and the VentriClear II Ventricular Catheter (K160223). The IRRAflow CNS System has the same indications for use, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the IRRAflow CNS System and the predicate devices raise no new issues of safety or effectiveness.