November 15, 2019

IRRAS USA, Inc.
Niloufa Insanally
Head of Regulatory Affairs
11975 El Camino Real, 3rd Floor
San Diego, California 92130

Re: K192289
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: August 21, 2019
Received: August 23, 2019

Dear Niloufa Insanally:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Director (Acting)
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K192289

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.

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

Applicant:

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FDA Registration #: 3013508628

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Date prepared: August 21, 2019

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):

IRRAflow® CNS System (K171880)

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.

SUBSTANTIAL EQUIVALENCE

The IRRAflow® CNS system's intended use, technological characteristics and principles of operation are the same as the predicate device.

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

Table 1 – Substantial Equivalence Comparison of the Monitoring Systems

Items	PREDICATE IRRAflow® CNS System (K171880) (JXG), (GWM)	IRRAflow® CNS System (JXG), (GWM) (New)	Equivalence
Primary Product	JXG	JXG	Same
Primary Regulation Number:	21 CFR 882.5550	21 CFR 882.5550	Same
Secondary Product	GWM	GWM	Same
Secondary Regulation Number:	21 CFR 882.1620	21 CFR 882.1620	Same
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.	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.	See discussion below
Injection/ CSF Sampling Ports	Yes	Yes	Same
Unidirectional Flow of Drained Fluid	Yes	Yes	Same
Fluid Injection Capability	Yes	Yes	Same
Attaches to separate, commercially available EVD Catheter	Yes The IRRAflow system attaches to IRRAflow Catheter which is an EVD Catheter part of the complete system.	Yes The IRRAflow system attaches to IRRAflow Catheter which is an EVD Catheter part of the complete system.	Same
Sterile Disposable tubing set	Yes	Yes	Same
CSF Drainage Bag	Yes	Yes	Same
Gravity drainage of	Yes	Yes	Same
Method to control gravity drainage of CSF	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.	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.	Same
Pressure Transducer for ICP Measurement	Yes (The IRRAflow system integrates transducers into its design for measurement and visual display of ICP)	Yes (The IRRAflow system integrates transducers into its design for measurement and visual display of ICP)	Same

Items	PREDICATE IRRAflow® CNS System (K171880) (JXG), (GWM)	IRRAflow® CNS System (JXG), (GWM) (New)	Equivalence
Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP	Yes	Yes	Same
Method to account for location of ventricles via patient head position	Reference marks on the device to allow for the system to be aligned with patient's head positioning.	Reference marks on the device to allow for the system to be aligned with patient's head positioning.	Same
Measured Pressure Range	-80 mmHg to +100 mmHg	-80 mmHg to +100 mmHg	Same
Displayed ICP	Yes	Yes	Same
Battery Back-up	Yes	Yes	Same

Discussion of differences in Table 1

IFU:

PREDICATE IRRAflow CNS system (K171880)	IRRAflow CNS system (New)	Discussion:
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.	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.	The difference in the indications for us in the duration of monitoring. The indications for use for the predicate (K171880) was ≤ 24 hours. Biocompatibility testing has been conducted and provided with this submission that the duration of use can be > 24 hours but less than or equal to 5 days.

EVD Catheter:

SUBSTANTIAL EQUIVALENCE

The IRRAflow® CNS System's Catheter technological characteristics and principles of operation are similar to the IRRAflow® CNS System Catheter (K171880). There have been no changes to the system catheter. The materials, design and principle of operations remain the same.

Comparison of these Catheters is provided in table 2 below

Table 2 – Substantial Equivalence Comparison – Catheters

Items	PREDICATE IRRAflow® CNS System Catheter (K171880)	IRRAflow® CNS System Catheter (New)	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	400mm	400mm	Same
Catheter Sideports	Yes	Yes	Same
Catheter End- hole	Closed	Closed	Same
Catheter Depth Markers	Yes	Yes	Same
Catheter material	Silicone	Silicone	Same
Antimicrobial Agents	None	None	Same
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	Same
Cytotoxicity	Acceptable	Acceptable	Same
Provided Sterile	Yes	Yes	Same
Packaging	Tyvek/polyester pouch	Tyvek/polyester pouch	Same
Functional Use	5 days	5 days	Same
Shelf Life	18 months	18 months	Same

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.
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.
Genotoxicity	The test was designed to screen the products and materials to determine if they cause structural chromosome aberrations in industry standard Chinese Hamster Ovary (CMC) cells.	**PASS** Clinical Observations: All test method acceptance criteria were met.
Implant Study	This study was conducted for test of local effects after implantation.	**PASS** Clinical Observations: All test method acceptance criteria were met.
Subacute Toxicity	The purpose of this study is to closely examine the toxicological hazard and to evaluate and address any risks associated with the biological endpoints of subacute/subchronic and chronic toxicity.	**PASS** Clinical Observations: All test method acceptance criteria were met.

Test	Test Method Summary	Results
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.
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.

Previous 510(k) Clearances:

The following are a list of the clearances for the Products discussed in this document:

Product	Clearance Number	Date
IRRAflow® CNS System	K171880	07/13/2018

Recognized Consensus Standards:

The IRRAflow® CNS System was developed in compliance with the following standards:			
Standard	**FR Recognition List Number**	**FR Recognition Number**	**Date of Recognition**
ISO 10993-1 Fourth Edition 2009-10-15, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]	044	2-220	07/26/2016
ISO 10993-3 Third Edition 2014-10-1, Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity	044	2-228	07/26/2016
ISO 10993-4 Third Edition 2017-04 Biological Evaluation Of Medical Devices--Part 4: Selection Of Tests For Interactions With Blood	047	2-248	08/21/2017
ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	046	2-245	12/23/2016
ISO 10993-6 Third Edition 2016-12-01, Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation	047	2-247	08/21/2017
ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	044	2-174	07/26/2016
ISO 10993-11 Second Edition 2006-08-15, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	044	2-176	07/26/2016
ISO 10993-12 Fourth Edition 2012-07-01, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials	044	2-191	07/26/2016
ISO 10993-12 Fourth Edition 2012-07-01, Biological Evaluation Of Medical Devices - Part 12: Sample Preparation And Reference Materials	044	2-191	07/26/2016
ISO 11135 Second Edition 2014, Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices	041	14-452	04/04/2016
ISO 11137-1 First Edition 2006-04-15, Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2013)]	041	14-428	04/04/2016

The IRRAflow® CNS System was developed in compliance with the following standards:			
Standard	**FR Recognition List Number**	**FR Recognition Number**	**Date of Recognition**
ISO 11137-2 Third Edition 2013-06-01, Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose	041	14-409	04/04/2016
ISO 11607-1 First Edition 2006-04-15, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]	038	14-454	01/27/2015
ISO 14971 Second Edition 2007-03-01, Medical Devices - Application Of Risk Management To Medical Devices	043	5-40	06/27/2016
60601-1:2012, Medical Electrical Equipment – Part 1: General Requirements for Safety and essential performance	036	19-4	07-09-2014
60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests	050	19-8	09/17/2018
60601-1-8:2006 & A1:2012, Medical Electrical Equipment -- Part 1-8: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equip.	031	5-76	08/06/2013

Conclusion:

The IRRAflow® CNS System is substantially equivalent to the predicate device (K171880). The IRRAflow® CNS System has the same intended use, technological characteristics, and principles of operation as the predicate devices. The minor differences in the indications for use between the IRRAflow® CNS System and the predicate device raise no new issues of safety or effectiveness.