October 19, 2023

IRRAS USA Inc.
Jeanne Warner
VP, Clinical & Regulatory Affairs
11975 El Camino Real, Suite 304
San Diego, California 92130

Re: K231664
Trade/Device Name: IRRAflow Active Fluid Exchange System (AFES)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG, GWM
Dated: September 15, 2023
Received: September 19, 2023

Dear Jeanne Warner:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.10.19 15:00:38 -04'00'

Adam D. Pierce, Ph.D.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231664

Device Name
IRRA*flow* Active Fluid Exchange System

Indications for Use *(Describe)*

The use of IRRA*flow* Active Fluid Exchange 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.

I. SUBMITTER

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Date prepared: October 18, 2023

II. DEVICE

Trade name: IRRA*flow*® Active Fluid Exchange System (AFES)

Common Name: CSF Drainage System with ventricular catheter
Regulatory Class: II

Primary Product Code: JXG (*21 CFR 882.5550 Central Nervous System Fluid Shunt and Components)*
Secondary Product Code: GWM *(21 CFR 882.1620 Intracranial Pressure Monitoring Device, per 21 CFR 807.92(a)(2))*

III. PREDICATE DEVICE

K222471, IRRA*flow* Active Fluid Exchange System

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The IRRA*flow*® Active Fluid Exchange System (AFES) is an intracranial pressure (ICP) monitoring and drainage system intended for use by professional medical hospital personnel, trained and experienced in neurosurgical medical care. The drainage flow of cerebrospinal fluid (CSF) into the IRRA*flow* 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 IRRA*flow* Tube Set has a cassette that clicks on to the IRRA*flow* Control Unit and aligns the tubing against a peristaltic pump and pinch valve. The IRRA*flow* Drainage Collection System is attached to the Control Unit, using the Laser Leveler for defining the height of the Drainage Collection System relative to the catheter's tip position in the patient's head. This positioning is used for 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 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 Drainage Collection System.

V. INDICATIONS FOR USE

The use of IRRA*flow*® Active Fluid Exchange 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The IRRA*flow*® AFES intended use, technological characteristics and principles of operation are the same or similar as those of the predicate device described in K222471 and the earlier device cleared in K200807 as shown for comparison in **Table 1**.

Comparison of these devices shows that the differences between the subject and predicate devices are the Tube Set and drainage bag components. designated as version 3.0. The currently cleared and marketed Tube Set is designated as version 2.0. Data presented definitively support the IRRAS conclusion that Tube Set version 3.0 continues to be as safe and effective as its cleared predecessor, Tube Set version 2.0.

Table 1: Substantial Equivalence (SE) Comparison

Item	IRRA*flow*® CNS System (K200807) (JXG), (GWM)	PREDICATE IRRA*flow*® AFES (K222471) (JXG), (GWM)	IRRA*flow*® AFES Traditional 510(k) K231664 (JXG),(GWM) Equivalence
Indications for Use	The use of IRRA*flow*® 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 use of the IRRA*flow*® Active Fluid Exchange 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.	Similar The use of IRRA*flow*® Active Fluid Exchange 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.
Injection/ CSF Sampling Ports	Yes	Yes	Yes
Unidirectional Flow of Drained Fluid	Yes	Yes	Yes
Fluid Injection Capability	Yes	Yes	Yes
Sterile Disposable Tube Set	Tube Set version 2.0	Tube Set version 2.0	Tube Set version 3.0
CSF Drainage Bag	Co-packaged with Tube Set version 2.0	Co-packaged with Tube Set version 2.0	Drainage Collection System Separately packaged
Gravity drainage of CSF	Yes	Yes	Yes
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.	Yes, 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.
Pressure Transducer for ICP Measurement	The IRRA*flow*® system integrates transducers into its design for measurement and visual display of ICP	The IRRA*flow*® system integrates transducers into its design for measurement and visual display of ICP	Yes, the IRRA*flow*® system integrates transducers into its design for measurement and visual display of ICP

Item	IRRA*flow*® CNS System (K200807) (JXG), (GWM)	PREDICATE IRRA*flow*® AFES (K222471) (JXG), (GWM)	IRRA*flow*® AFES Traditional 510(k) K231664 (JXG),(GWM) Equivalence
Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP monitoring	Yes	Yes	Yes
Measured Pressure Range	-80 mmHg to +100 mmHg	-100 to +300 mmHg	-100 to +300 mmHg
Displayed ICP	Yes	Yes	Yes
Battery Back-up for Control Unit	Yes	Yes	Yes

A review of **Table 1** shows that there is no change to the intended use of the IRRA*flow*® System. Changes made to the Tube Set and Drainage Collection System required additional testing, including verification and validation of continued functionality with material changes. There are no changes to the principles of operation of the IRRA*flow*® System. Any new safety and effectiveness issues related to the Tube Set and Drainage Collection System modifications are addressed in the FMEA and Risk Analysis. **Table 2** provides a comparison of the Tube Set 2.0 characteristics to those of the Tube Set 3.0.

Table 2: Tube Set 2.0 and Tube Set 3.0 Comparison

Device characteristic	Tube Set 2.0 Predicate	Tube Set 3.0 K231664	Rationale
1. Revision of the internal fluid-contacting pinch valve ball 2.5 mm diameter stainless-steel ball	Stainless Steel 440C	Corrosion resistant Stainless Steel Alloy 316L	This material change will prevent component corrosion during the life cycle of the device.
2. Modification of the sensor housing clamp	Wedge to wedge pinch clamp (sensor housing to calibration hub). The two wedges becoming offset will result in failure to achieve appropriate pinch pressure to halt flow, resulting in leakage out of the atmospheric port at clinically relevant temperatures.	Modified Sensor Clamp, Cassette	Improved leak resistance
3. Addition of a protective layer of heat shrink tubing to pressurized manifold barb connections.	No heat shrink protective layer	Heat shrink protective layer, compatible with normal physiological pressure range during use, and designed to withstand -110 to +550mmHg pressure without mechanical damage such as tubing collapse or bursting	Improved device performance at high pressures; heat shrink will act as a secondary protection to prevent leaks when high pressures are inadvertently applied to the device.
4. Improved the fluid flow through the irrigation line by removing the check valve between the irrigation spike and cassette.	In line irrigation tubing check valve	Check valve removed from irrigation line tubing	The head pressure of a full irrigation bag (1000mL) with a fully extended irrigation tubing is 1.15 psi. The cracking pressure of the specified check valve (1.5 – 5psi) is overqualified for this use case, causing turbulent flow past the check valve leading to the formation of small to large air bubbles in the irrigation line.
5. Addition of molded strain reliefs	Non-molded strain relief	Molded strain relief - the fit, form and	Added to improve the device performance,

Device characteristic	Tube Set 2.0	Tube Set 3.0	Rationale
		function of the strain relief has not changed. Strain relief will now be molded for ease of manufacturing.	and for ease of manufacturing
6. Removal of luer connections	Luer connections between the Cassette and Catheter on the irrigation line, and the pinch clamp between the irrigation bag and cassette on the irrigation line have been removed	No luer connections	These components are not required for system function or performance
7. Addition of Labels to tubing lines	Irrigation and drainage lines without labels	Labels on tubing lines: identifies irrigation tubing, drainage tubing and drainage bag tubing	Improved usability
8. Addition of a Tyvek sleeve, provided in the tube set assembly	No Tyvek sleeve in tube set assembly	Tyvek sleeve in tube set assembly	To protect the irrigation to drainage line tube connection from accidental sterile field failures during priming
9. Length of tube lines on the catheter side of the cassette	Current length of tubing lines on catheter side of the cassette are 47 inches/1195 mm ± 20.	Increased length by 12 inches; the length of irrigation and drainage tubing on the catheter side of the component is now 1500 mm ± 20.	To allow for typical patient care procedures with associated patient position changes
10. Drainage bag	Tube Set 2.0 is co-packaged and sterilized with the drainage bag	Tube Set 3.0is packaged separately from the Drainage Collection System	Allows for independent replacement of these system components when indicated
11. Packaging upgraded to meet brand standards.	Tyvek pouch only	More durable Tyvek pouch with the product mounted on a labeled presentation card. A new 1-up carton, and 5-up shipper will be used for shipping.	The labeled presentation card will help maintain sterility during system set-up and add guidance on how to properly set up the device

Device characteristic	Tube Set 2.0	Tube Set 3.0	Rationale
12. Increased shelf life	Shelf life set at 18 months	Shelf life extended to 36 months	Real time and accelerated aging studies support 36 month expiry for sterile packaging

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination (**Table 3**).

Table 3: Testing Summary

Test	Test Method Summary	Results
Biocompatiblity Testing		
Cytotoxicity	The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances.	**PASS**
Sensitization Test	This test was designed to evaluate the allergenic potential or sensitizing capacity of a test article.	**PASS**
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**
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**
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**
Genotoxicity	The purpose of the study is to evaluate the potential mutagenicity of the test article extract on various strains of bacteria.	**PASS**
Genotoxicity	The purpose of the study is to evaluate the potential mutagenicity effect of the test article extract on mouse lymphoma cells	**PASS**
Bench and Electrical Testing		
Electrical Requirements Verification	Pressure accuracy per protocol	**PASS**
Mechanical Performance Verification	Durability, flow and freedom from leakage per protocol	**PASS**
Life Cycle Verification Test	Simulated use testing to demonstrate lifecycle reliability	**PASS**
Shelf Life / Package Integrity Testing		
Simulated Distribution Test	ASTM D4332-14 ASTM D4169-22 Cycle 13	**PASS**
Package Integrity Test	ASTM F1886-16 ASTM F2096-11	**PASS**
Package Seal Strength Test	EN 868-5:2009	**PASS**
Aging Test	Accelerated and real time aging	**PASS**
Sterilization Testing		
Sterilization Process for the IRRAflow Intelligent Cassette and IRRAflow Drainage Collection System	Study conducted to validate the effectiveness of Ethylene Oxide sterilization of IRRAflow Intelligent Cassette and IRRAflow Drainage Collection System	**PASS**

Conclusion

The IRRA*flow*® AFES is substantially equivalent to the predicate device (K222471). The IRRA*flow*® AFES has the same Indications for Use, similar technological characteristics, and the same principles of operation as the predicate device. Performance testing demonstrates the changes to the Tube Set designated as version 3.0 and Drainage Collection System do not change or adversely impact the operational parameters of the IRRA*flow*® System.