December 8, 2022

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

Re: K222471
Trade/Device Name: IRRAflow Active Fluid Exchange 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: November 4, 2022
Received: November 7, 2022

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 (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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2022.12.08 07:36:05 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number
K222471

Device Name
IRRA*flow* Active Fluid Exchange System

Indications for Use *(Describe)*

The use of IRRAflow 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.

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

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510(k) Summary

Applicant:

IRRAS USA, Inc.
11975 El Camino Real, Suite 304
San Diego, CA 92130
US.A
Phone Number: 858-220-3761
Fax number: 866-575-1002
FDA Registration#: 3013508628

Primary Contact Personnel:

Jeanne S. Warner, RN MS
VP, Clinical & Regulatory Affairs
Phone Number: 269-270-2189
Fax Number: 866-575-1002
Email: jeanne.warner@irras.com

Secondary Contact Personnel:

Fernando Sanchez
Sr. Director, Quality
Phone Number: 858-212-6660
Email: fernando.sanchez@irras.com

Date prepared: December 8, 2022

510(k) Number: K222471

Trade name: IRRA*flow*® Active Fluid Exchange System (AFES, formerly branded as 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

Primary Predicate Device: IRRAflow® CNS System, K200807

Additional Predicate Device: IRRAflow® CNS System, Kl92289

1.0 DEVICE DESCRIPTION - IRRA*flow*® Active Fluid Exchange System

The IRRA*flow*® Active Fluid Exchange System (formerly branded as the CNS System) is an intracranial pressure (ICP) monitoring and drainage system, substantially equivalent to the predicate 510(k) K200807. Changes described herein were evaluated using design controls. 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. A drainage bag is attached to the Control Unit, using the Laser Leveler for defining the height of the bag 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 aspiration port.

2.0 INDICATIONS FOR USE

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.

3.0 SUBSTANTIAL EQUIVALENCE

The IRRA*flow*® AFES (formerly branded as CNS System) intended use, technological characteristics and principles of operation are the substantially equivalent to the predicate device described in K200807. Changes present in the Control Unit 4.0 that would have potential to affect the technological characteristics or principles of operation of the IRRA*flow*® System were evaluated by design controls. Earlier predicate devices described in K192289 and K200807 are shown for comparison in **Table 2** below.

Comparison of these Monitoring Systems will show that the only difference in the device presented in this Special 510(k) are the enhanced and new features present in the Control Unit, designated as version 4.0. The currently cleared and marketed Control Unit is designated as version 3.0. Data presented definitively support the conclusion that Control Unit version 4.0 continues to be as safe and effective as the predicate device.

Therefore, this Special 510(k) captures detailed descriptions of changes to the Control Unit which is part of the overall IRRA*flow*® AFES, classified by FDA as a Class II medical device. IRRAS is submitting this Special 510(k) as substantially equivalent to the IRRA*flow*® CNS System device described in K192289 and K200807.

Table 2: Substantial Equivalence (SE) Comparison

Attributes	PREDICATE IRRA*flow*® CNS System (K192289) (JXG), (GWM)	PREDICATE IRRA*flow*® CNS System (K200807) (JXG), (GWM)	IRRA*flow*® AFES System Special 510(k) K222471 (JXG), (GWM) Equivalence
Primary Product Code	JXG	JXG	JXG
Primary Regulation Number:	21 CFR 882.5550	21 CFR 882.5550	21 CFR 882.5550
Secondary Product Code	GWM	GWM	GWM
Secondary Regulation Number:	21 CFR 882.1620	21 CFR 882.1620	21 CFR 882.1620
Indications for Use	The use of IRRA*flow*® CNS 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.	Same The use of IRRA*flow*® CNS 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.	Same The use of IRRA*flow*®AFES 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. **

Attributes	PREDICATE IRRAflow® CNS System (K192289) (JXG), (GWM)	PREDICATE IRRAflow® CNS System (K200807) (JXG), (GWM)	IRRAflow® AFES System Special 510(k) K222471 (JXG), (GWM) Equivalence
Injection/ CSF Sampling Ports	Yes	Yes	Yes
Unidirectional Flow of Drained Fluid	Yes	Yes	Yes
Fluid Injection Capability	Yes	Yes	Yes
Attaches to separate, commercially available EVD Catheter	The IRRA*flow*® system attaches to IRRA*flow*® Catheter which is an EVD Catheter part of the complete system.	Same, the IRRA*flow*® system attaches to IRRA*flow*® Catheter which is an EVD Catheter part of the complete system.	Same, the IRRA*flow*® system attaches to IRRA*flow*® Catheter which is an EVD Catheter part of the complete system
Sterile Disposable tubing set	Yes	Yes	Yes
CSF Drainage Bag	Yes	Yes	Yes
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.	Same, 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, 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	Same, the IRRA*flow*® system integrates transducers into its design for measurement and visual display of ICP	Same, the IRRA*flow*® system integrates transducers into its design for measurement and visual display of ICP.

Attributes	PREDICATE IRRAflow® CNS System (K192289) (JXG), (GWM)	PREDICATE IRRAflow® CNS System (K200807) (JXG), (GWM)	IRRAflow® AFES System Special 510(k) (GWM, JXG) Equivalence
Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP monitoring	Yes	Yes	Substantially equivalent to predicate, with addition of: • Bedside monitoring ability (BSMA)to export ICP data stream compatible with marketed bedside monitors, with cables • Increased volume for system alarms • Power system changes to extend shelf life and improve power shut down sequencing • Allowance for 'off the shelf' external power supply • Manufacturability related changes to board layout • Bluetooth hardware for future application development • User software enhancements, including: case-specific irrigation and drainage settings, additional data visualization onscreen (trending, axis and unit adjustments), auto priming cassette functionality, pressure accuracy improvement • Drainage collection system mounting that allows enhanced fluid drainage collection
Measured Pressure Range	-80 mmHg to +100 mmHg	Same, -80 mmHg to +100 mmHg	Substantially Equivalent -100 to +300 mmHg
Displayed ICP	Yes	Same	Same
Battery Back-up	Yes	Yes	Same

** Equivalent-change *from* CNS System *to* Active Fluid Exchange System is a branding change only

A review of **Table 2** shows that there is no change to the overall IRRA*flow*® system. Changes made only to the Control Unit software required additional testing, including verification and validation of new and enhanced functionality. Changes present in the Control Unit 4.0 that would have potential to affect the technological characteristics or principles of operation of the IRRA*flow*® System were evaluated by design controls. Any new safety and effectiveness issues related to the Control Unit modifications are addressed in the FMEA and Risk Analysis.

Because changes were made only to the Control Unit software (with minor hardware changes to accommodate hanger for drainage bag and Scale), with the required additional testing including verification and validation new and enhanced functionality, the continued safe and effective use of Control Unit 4.0 was confirmed. Changes present in the Control Unit 4.0 that would have potential to affect the technological characteristics or principles of operation of the IRRAflow® System were evaluated by design controls. Any new safety and effectiveness issues related to the Control Unit modifications are addressed in the Control Unit FMEA. No changes were made to the EVD catheter or the remaining components of the IRRA*flow*® system.

4.0 SUMMARY OF DESIGN CONTROLS

Procedural design controls were followed, and all design elements were satisfied.

5.0 SUMMARY OF VERIFICATION & VALIDATION

Additional verification and validation performance testing was done on the IRRA*flow*® AFES Control Unit 4.0. Any new safety and effectiveness issues related to software and other described changes were addressed in the FMEA and Risk Analysis.

The IRRA*flow*® AFES is substantially equivalent to the system described in 510(k) K200807. Enhanced and new Control Unit features are described herein. These changes do not adversely affect the safety and effectiveness of the IRRA*flow*® Control Unit. Any new risks to the overall system were address in the FMEA and Risk Analysis. The risk was evaluated separately, as well as, in conjunction with the system components of the IRRA*flow*® AFES. Since any new concerns or risks identified were mitigated by the actual proper use and function of Control Unit 4.0, it is appropriate to conclude that the IRRA*flow*® AFES is Substantially Equivalent to the predicate device (K200807).

A summary of the testing done at IRRAS is presented in the Table below. In **Table 4** below, IRRAS has identified the various well-established and recognized Standards for evaluation of the performance of the Control Unit 4.0 separately. Results are provided in a summary format. Complete test reports are available upon request.

Table 4: Control Unit 4.0 Testing Summary

Test	Test Method Summary	Results
Verification by Inspection	No physical testing is performed for the associated requirements. Coverage was demonstrated by analysis and presented in a final trace matrix.	Acceptable
BSM Requirements Verification	These testes are algorithmic in nature, with demonstration of passing results one one sample, with repeated tests as defined in the associated protocol, are valid for full requirement coverage.	Pass
Electrical Requirements Verification		
Mechanical Performance Verification	As defined in the associated protocol, the requirement pertains to the hardware component itself (i.e. pole clamp, drainage bag holder clip, etc.) and not on its interface with the control unit.	Pass
Life Cycle Verification Test	All testing was completed on capital equipment, with multiple test repeats (as required) were used to demonstrate lifecycle reliability.	Pass
Packaging Verification	No risk to user since device was found to work based on device functionality checked upon arrival after simulated transit.	Pass

Conclusions

The IRRA*flow*® AFES (formerly branded as the CNS system) is Substantially Equivalent to the predicate device (K200807). The IRRA*flow*® AFES has the same Indications for Use. Changes present in the Control Unit 4.0 that would have potential to affect the technological characteristics or principles of operation of the IRRA*flow*® System were evaluated by design controls.