April 29, 2020

IRRAS USA Inc.
Niloufa Insanally, Ph.D., RAC
Head of Regulatory Affairs
11975 El Camino Real, Suite 304
San Diego, California 92130

Re: K200807
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: March 28, 2020
Received: March 30, 2020

Dear Dr. 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., M.S.
Director
DHT5A: Division of Neurosurgical,
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200807

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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Date prepared: February 07, 2020

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, K192289)

DEVICE DESCRIPTION – IRRAflow CNS System

The IRRAflow® CNS System is an intracranial pressure (ICP) monitoring and drainage system, and remains identical, as cleared under predicate 510(k) K192289. 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 described in K192289. For ease of reading, both earlier predicate devices described in K171880 and K192289 are shown for comparison in Table 1 below.

Comparison of these Monitoring Systems will show that the only difference in the device presented in this Special 510(k) is the inclusion of the Laser Leveler Accessory tool, which supports and augments the IRRAflow CNS system by providing a more accurate and easier method for positioning the control unit (or drainage system) with the patients external auditory meatus (or external ear canal). Using the laser leveler tool, the drainage system can be raised or lowered until the laser light points horizontally to the correct landmark on the patient's head. The common landmark used is the external auditory canal.

The earlier methods used for this alignment involved the placement of a taut string from the patient's head to the drainage system. This method for alignment may still be used. However, the laser leveler alignment tool presents a better method for this alignment step which is performed when the instrument is set up. The IRRAflow Control Unit was originally designed with a screw connection port which would hold the laser leveler tool, and IRRAS's earlier intention was to submit the laser leveler tool along with the most recent 510(k) submission (K192289) in August 2019, but the testing for the laser leveler tool was not completed at the time of the K192289 submission.

Therefore, this Special 510(k) captures the information related to the laser leveler accessory which is part of the overall IRRAflow CNS System that was originally classified by FDA as a Class II medical device. Traditionally, FDA has been able to classify accessories within the same classification as the parent device and for this reason, IRRAS is submitting this Special 510(k) as a follow up adjunct to the IRRAflow CNS System device described in K192289.

Table 1 – Substantial Equivalence Comparison of the Monitoring Systems

Items	PREDICATE IRRAflow® CNS System (K171880) (JXG), (GWM)	PREDICATE IRRAflow® CNS System (K192289) (JXG), (GWM)	IRRAflow® CNS System Special 510(k) (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	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.	Same as for K192289
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 CSF	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

Items	PREDICATE IRRAflow® CNS System (K171880) (JXG), (GWM)	PREDICATE IRRAflow® CNS System (K192289) (JXG), (GWM)	IRRAflow® CNS System Special 510(k) (JXG), (GWM) Equivalence
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
Software-based, Powered Console for User Interface, User Settings and Alarm Adjustments, Data Storage and Display, and Alarms for ICP Monitoring	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" + Alternative method to use the Laser Leveler accessory to position the system (control unit) with the patient's head.
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

An inspection of Table 1 will show that there is no change in the actual IRRAflow CNS System so that no additional testing (or verification and validation testing) on the CNS system was required. There are no changes to the technological characteristics or principles of operation of the drainage system itself; no new safety and effectiveness issues are raised with this new device. The only change was to add a separate tool, the IRRAflow laser leveler, to the overall system to facilitate the alignment of the drainage system with the patient's head at the beginning of the setup of the system (refer to redlines in Table 1).

Discussion of differences in Table 1

Method to account for location of ventricles via patient head position		
IRRAflow CNS system (K171880)	**IRRAflow CNS system (K192289)**	**IRRAflow CNS system Special 510(k)**
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.	***Discussion:*** Same as for predicate(s) but also added the use of the Laser Leveler tool to adjust positioning of IRRAflow CNS system so that it is aligned with patient's head (external auditory meatus).

It should be noted that the earlier methods involving a line level measurement which employs a taut string can still be used for alignment, but the laser leveler tool presents an alternative and better method for alignment of the drainage system with the patient's head.

Therefore, there is no change in the overall IRRAflow CNS system, except for the addition of an accessory to aid in positioning of the drainage system in alignment with the location of the ventricles in the patient's head. The use of the laser leveler is an additional option for location of the ventricles via the patient head position.

Use of the The IRRA*flow*® Laser Leveler

The IRRAflow® laser leveler is a reusable accessory to be utilized in conjunction with the IRRAflow® CNS system. The laser leveler generates a laser mark to assist in setting the height of the control unit. The IRRA*flow*® Laser Leveler device is provided with a mounting screw for use with the The IRRA*flow*® CNS control unit. The laser leveler has a power button and auto shuts off after approximately 20 seconds.

The control unit has a screw connection on the side of the unit and the laser leveler has a shoulder screw which can be screwed into the control unit using an Allen wrench. Once attached to the control unit, the control unit assembly can be moved up and down on an IV pole, and the laser leveler should swing freely (it is weighted down). The laser leveler may then be used to auto align the control unit assembly to the patient's head.

The laser light is turned on and remains on for a maximum of 20 seconds, during which time the emitted light is pointed directly to the patient's external auditory meatus (in order to align with the patient's ventricles). Once the control unit drainage system is aligned horizontally with the patient's auditory meatus, the assembly is locked into position. The laser automatically shuts off after 20 seconds, the laser light will disappear, and the drainage system will be ready to operate.

No changes were made to the EVD catheter or the IRRAflow CNS system.

1. **EVD Catheter:**
   The IRRAflow® CNS System's Catheter technological characteristics and principles of operation are identical to the IRRAflow® CNS System Catheter (K192289). There have been no changes to the system catheter. The materials, design and principle of operations remain the same.

2. **Verification and Validation Documentation for the IRRAflow CNS System:**
   Similarly, the addition of the laser leveler accessory does not change or impact any of the verification and validation testing performed earlier on the IRRAflow® CNS System. The verification and validation performance testing which was performed earlier (refer to K192289) has not changed. In conclusion, the IRRAflow® CNS System is substantially equivalent to the predicate device.

3. **Verification and Validation testing for the Laser Leveler:**
   While no changes were made to the IRRAflow CNS System as a whole, and therefore no additional verification and validation testing was required for the system, there was verification and validation testing performed during the design of the laser leveler accessory. Development and testing for the laser leveler was performed at a contract manufacturer, Meraqi Medical, Inc. (Freemont, CA). The laser testing was performed at a sub-contractor, Intertek (Menlo Park, CA). The design of the laser leveler was performed at IRRAS and transferred to Meraqi Medical for development (including design controls), testing and subsequently, manufacturing.

SUMMARY OF VERIFICATION & VALIDATION FOR THE LASER LEVELER

No additional verification and validation performance testing was done on the IRRAflow® CNS System itself since no new safety and effectiveness issues were raised with the 'new' device. The IRRAflow CNS System remains the same as described in 510(k) K192289. The only change is the addition of the laser leveler accessory. The only new risks to the overall system with the inclusion of the laser leveler accessory, is the introduction of laser energy in the system and the risk posed by exposing the patient to laser light. The risk was evaluated separately, as well as, in conjunction with the laser leveler tool being used in the initial setup of the IRRAflow CNS system. Since no new concerns or risks were identified that could not be mitigated by the actual proper use and function of the laser leveler, and there were built-in fail safes in the laser leveler (i.e. the laser light automatically turns off after 20 seconds), one may conclude that the IRRAflow® CNS System is substantially equivalent to the predicate device (K192289).

However, a full analysis of the laser leveler was performed, and a summary of the testing done at Meraqi Medical and Intertek is presented in Table 2 below.

It is important to note that since no new performance data for the actual IRRAflow CNS system are needed to evaluate the change (i.e. use of the laser leveler accessory with the IRRAflow CNS system), the submission of a Special 510(k) is appropriate in this case. Furthermore, in Table 2 below, IRRAS has identified the various well-established and recognized standards which allow one to evaluate the performance of the laser leveler accessory separately. The data or results are provided in Table 2 in a summary format.

Table 2 – Laser Leveler Testing Summary

Test	Test Method Summary	Results
Dimensional	Verify units meet dimensional specification.	Pass
Visual (laser)	Verify units have legible labeling and are free of damage and/or foreign particulate.	Pass
Visual (Packaging)	Verify packaging is free of damage and labels are legible	Pass
Functional Testing	Functional testing includes: button press, vertical position test, laser spot alignment, auto shutoff test, trunnion articulation.	Pass
IEC 60825-1	Laser safety testing: Wavelength and conformance to IEC 60825-1 standard	Pass
IEC 60529 (IP22)	Fluid ingress testing: Verify conformance to the IP2X requirements of IEC 60529 Edition 2.2.	Pass
ASTM D4332-14-Package environmental conditioning	2014 Version - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing Conduct the conditioning test per ASTM D4332-14 on the packages: Extreme Cold: -30°C, uncontrolled RH for 24 hours Tropical: +40°C, 90% RH for 24 hours Desert: +60°C, 15% RH for 24 hours Chamber Class: 3 Notes: Westpak calls out tolerances of ±2°C and ±5% RH.	Pass
ASTM D4169-16, Distribution cycle 13	2016 Version- Air (intercity) and motor freight (local), single package up to 150 lb. (61.8 kg)	Pass
Schedule A Initial manual handling – ASTM D5276-98 Box	Impact Quantity: Six (6) Top, Two adjacent bottom edges, two diagonally opposite bottom corners, bottom Drop height: dependent on weight per procedure	Pass
Schedule C Vehicle stacking- ASTM D642-15	The package systems will be compressed per the computed load value in section 11.4.	Pass
Schedule F Loose load vibration – ASTM D999-08	Method A2 - Repetitive Shock Test (Rotary Motion) Duration: 60 min (AL I) Dwell time distributed 50% along predetermined bottom orientation facing down and remaining 50% evenly along side and end orientations.	Pass

Test	Test Method Summary	Results
Schedule I Low Pressure Test- ASTM D6653-13	14,000 Feet (446 torr) 60 minute dwell, 1,000 to 2,000 feet per minute ramps	Pass
Schedule E Vehicle Vibration – ASTM D4729-17 Truck and Air	Truck Spectrum Low Frequency Range: 1-200 Hz Overall Intensity: 0.40 Grms Truck Spectrum Medium Frequency Range: 1-200 Hz Overall Intensity: 0.54 Grms Truck Spectrum High Frequency Range: 1-200 Hz Overall Intensity: 0.70 Grms Air Spectrum Frequency Range: 2-300 Hz Overall Intensity: 1.49 Grms (Assurance Level I) Durations as outlined per standard.	Pass
Schedule J Concentrated Impact – ASTM D6344-04	Cylindrical mass Drop Height: 32 inches (5.4 J) Box: All 6 faces Plastic Wrapped Unitized Loads: All wrapped faces (excluding base) Note: This test will be omitted if the shipper is a doublewall shipper OR a singlewall shipper and has a Mullen Burst Strength equal to or greater than 275 psi/44 ECT.	Pass
Schedule A Final Manual handling – ASTM D5276-99 Box	Box Impact Quantity: Six (6) Vertical edge, Two adjacent side faces, one top corner, one adjacent top edge, *bottom Drop height: dependent on weight per procedure *The last impact should be made at twice the specified height.	Pass
ASTM F19880-16 Accelerated Aging Testing	2016 Version - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices Conduct the accelerated aging test per ASTM F1980-16 on the packages: 6-Month Accelerated Aging (Desired Real Time) Accelerated Aging Duration: 10 (days) Accelerated Aging Temperature (TAA): +65°C Accelerated Aging Relative Humidity (RH): Uncontrolled Real Time Room Temperature (TRT): +23°C Q10: 2 Volume: 3 cu ft Note: Westpak calls out tolerances of ±2°C.	Pass

Conclusion

The IRRAflow® CNS System is substantially equivalent to the predicate device (K192289). The IRRAflow® CNS System has the same indications for use, technological characteristics, and principles of operation as the predicate device. The addition of the laser leveler accessory does not change or impact the operational parameters of the IRRAflow CNS System, but it does add an additional option to assess the position of the drainage system with the landmark target on the patient's head during initial setup. The positioning of the drainage system with the external auditory meatus of the patient's head is facilitated by use of the laser leveler.