December 10, 2025

BrainSpace, Inc.
Caitlin Morse
CEO
22121 17th Avenue SE, Suite 112
Bothell, Washington 98021

Re: K251598
Trade/Device Name: Intellidrop
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 12, 2025
Received: November 12, 2025

Dear Caitlin Morse:

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 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.

All medical devices, including class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

XIAOLIN
ZHENG -S

For Jaime Raben, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251598

Device Name

Intellidrop

Indications for Use *(Describe)*

The Intellidrop system is indicated for use to provide external drainage of cerebrospinal fluid (CSF) and/or monitoring of CSF drainage and intracranial pressure (ICP) for ventricular or lumbar use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (K251598)

General Information:

Date of Summary:	December 9, 2025
Name and Address of Manufacturer:	BrainSpace Inc. 22121 17th Ave SE, Suite 112 Bothell, WA 98021, USA 425.725.5008
Contact Person:	Caitlin Morse, CEO
Trade Name:	Intellidrop
Common Name:	External CSF Drainage System
Regulation Number, Primary:	21 CFR 882.5550
Product Code, Primary:	JXG
Regulation Description:	Central Nervous System Fluid Shunt & Components
Regulatory Class, submission:	Class II, Tradition 510(k)
Classification Panel:	Neurology
Additional Associated Product Code:	GWM

Device Description:

The Intellidrop system continuously monitors intracranial or spinal pressure and manages external drainage of cerebrospinal fluid (CSF) and other body fluids to a user-selected pressure target or volume target.

Key features of the Intellidrop include:

- Wearable sensor array facilitating position-agnostic pressure monitoring
- Closed-loop, gravity-based drainage to a pressure or volume target
- Real-time display of intracranial pressure (ICP) waveform
- Historical trend data of daily, hourly, and minute-by-minute ICP and drainage volume
- User selectable audio-visual alarm thresholds for both pressure and volume
- Patented Continuous Drift Detection Technology
- Continuous operation on AC power and up to 4 hours of continuous operation on rechargeable battery power
- Real-time data streaming of ICP to a patient monitor via cable
- Proximal sampling port and optional distal sampling port

Indications for Use:

The Intellidrop system is indicated for use to provide external drainage of cerebrospinal fluid (CSF) and/or monitoring of CSF drainage and intracranial pressure (ICP) for ventricular or lumbar use.

Predicate Device:

- Smart External Drain (SED) System by Aqueduct Critical Care Inc. (K172759)

The BrainSpace Intellidrop is substantially similar to the predicate. The intended use and patient populations are identical and the minor differences in technical characteristics do not generate new questions of safety or effectiveness. Refer to *Table 1* for details.

Table 1: Comparative Summary of the BrainSpace Intellidrop to Predicate Device

Description	**Predicate: SED System by Aqueduct Critical Care, Inc. (K172759)**	**Subject Device: BrainSpace Intellidrop**
Device Trade Name	Smart External Drain (SED) System	Intellidrop
Intended Use	External ventricular or lumbar drainage of cerebrospinal fluid (CSF) and monitoring of CSF drainage and/or pressure.	Same as predicate
Attaches to separate commercially available catheter	Yes	Same as predicate
Sterile disposable tubing set	Yes	Same as predicate
CSF drainage bag	Yes	Same as predicate
Gravity drainage of CSF	Yes	Same as predicate
Method to control gravity drainage of CSF	Yes – automated adjustment based on user settings via an actuator-controlled tube pinching mechanism in the console to either compress or release the compliant drainage tubing contained within the cartridge.	Same as predicate
Pressure transducer for ICP measurement	Yes	Same as predicate
Pressure Anatomical Alignment Method	Disposable includes wearable reference at level of EAM (external auditory meatus).	Disposable includes wearable transducer at level of EAM (external auditory meatus).
Software-based powered console for user interface, ICP target and alarm settings, data storage and display, and alarms	Yes	Same as predicate
Pressure Target Range	-5 to 40 cm H_2O (ventricular only)	-20 to 50 cm H_2O (ventricular only)
Hourly Drainage Volume Range	0 to 45 mL/hr	0 to 60 mL/hr
Displayed ICP	Yes	Same as predicate
Battery backup	Yes	Same as predicate

Testing Summary:

The testing presented confirm substantial equivalence to the predicate in terms of biocompatibility, electrical safety, resistance to electromagnetic interference, packaging, sterilization, shelf-life and performance to specifications and key consensus standards. Therefore, the sum of the presented test data is sufficient to demonstrate intended device performance. Refer to *Table 2* for details.

Table 2: Summary Table for BrainSpace Intellidrop Testing

Test	Test Summary	Result / Conclusion
Electrical Safety	Basic safety and essential performance of the system was completed in accordance with IEC 60601-1: Edition 3.2, 2020, and relevant sub-parts.	Pass – Fully compliant
Storage and Transit Simulation	Accelerated shelf-life conditioning and transit simulation were completed as applicable and the system confirmed fully functional.	Pass – All requirements met for the duration of labeled shelf-life
Sterility	The patient interface disposable of the Intellidrop system was sterilized via ethylene oxide (EO) sterilization and assessed for cycle effectiveness in accordance with ISO 11135: 2014/A1: 2018.	Pass - Fully compliant Disposable confirmed sterile
Sterile Barrier Performance	The sterile barrier of the patient interface disposable was assessed and confirmed appropriate to maintain sterility in accordance with ISO11607: 2019.	Pass – All requirements verified Disposable packaging confirmed to maintain sterility
Biocompatibility	Biocompatibility testing was performed based on risk assessment and in accordance with ISO 10993-1:2018 and associated sub-parts.	Pass – System is biocompatible and non-pyrogenic
Cleanability	The reusable console was assessed for cleanability.	Pass – All requirements verified
Magnetic Resonance (MR) Compatibility	MRI compatibility was assessed and the system confirmed as MR Conditional in accordance with ISO TS 10974: Ed. 2: 2018.	MR Conditional
Basic Safety	The Intellidrop system was tested for basic safety and maintenance of essential performance in accordance with IEC 60601-1: Edition 3.2: 2020.	Pass – Fully compliant
Electromagnetic Interference and Immunity	The essential performance of the Intellidrop system was assessed against the risk of electromagnetic interference in accordance with IEC 60601-1-2: 2014 and IEC TR 60601-4-2:2016.	Pass – Fully compliant

Test	Test Summary	Result / Conclusion
Software Verification and Validation	Software code verification, unit testing and system-based verification and validation testing for software controlled or impacted functions was completed, including user-interface review.	Pass – All requirements verified or validated
Functional Performance	Verification tests were performed on the Intellidrop system and sub-systems to confirm functional performance.	Pass – All requirements verified
Accuracy, Stability and Performance	The system was assessed for accuracy, stability, and durability of performance for up to 14 days (the longest expected per-patient use of the Intellidrop system) in accordance with AAMI NS28: 1988/R: 2015.	Pass – Fully compliant
Human Factors Usability Validation	Usability of the system and the effectiveness of provided information was assessed through summative human factors validation on select groups of users in accordance with IEC 62366-1:2015+AMDI:2020.	Pass – All requirements validated; all critical tasks successfully executed. System confirmed usable by the intended users.

Conclusion (Statement of Equivalence):
The data and information presented within this submission support a determination of substantial equivalence to the predicate.