DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 30, 2017

Aqueduct Critical Care, Inc.
Thomas Clement
President & CEO
11822 North Creek Parkway North, Suite 110
Bothell, Washington 98011

Re: K171586
Trade/Device Name: Smart External Drain (SED) 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: May 30, 2017
Received: May 31, 2017

Dear Mr. Thomas Clement:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171586

Device Name
Smart External Drain (SED) System

Indications for Use *(Describe)*

Draining and monitoring of CSF flow from the lateral ventricles is indicated in selected patients to:

- Reduce intracranial pressure (ICP), e.g., pre-, intra- or postoperative.
- Monitor CSF chemistry, cytology, and physiology.
- Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

Monitoring of intracranial pressure (ICP) is indicated in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage graded III, IV, or V preoperatively
- Reye's syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Miscellaneous problems when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions.

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.

510(k) Summary

General Information:

Date of Summary Preparation:	June 22, 2017
Name and Address of Manufacturer:	Aqueduct Critical Care, Inc. 11822 North Creek Parkway North Suite 110 Bothell, WA 98011
Contact Person:	Tom Clement, President and CEO Phone: 425-985-1571 Fax: 425-278-9377
Trade Name:	Smart External Drain (SED) System
Common Name:	External CSF Drainage System
Regulation Number:	Primary: § 21 CFR 882.5550 Secondary: § 21 CFR 882.1620
Regulation Description:	Central Nervous System Fluid Shunt and Components Intracranial Pressure Monitor
Regulatory Class:	Class II
Classification Panel:	Neurology
Product Code:	Primary: JXG Secondary: GWM

Device Description: The SED System is based upon traditional gravity-based drainage systems, but is designed to allow for the automated regulation of ICP without the need for continuous manual measurements, adjustments and interventions. The SED System consists of an electromechanical software embedded SED Console and a sterile, disposable SED Cartridge, which includes all components necessary to attach to the external ventricular drainage catheter via a luer-lock connector and to a drainage bag that collects the drained fluid.

The SED System is mounted on an IV pole, with the SED Console positioned by the user at an easy-to-view height, while the drainage bag is positioned below the lowest possible patient head position, which is considered to be below the height of a hospital bed.

The SED System automatically maintains a set ICP using pressure sensors (transducers) and an automated stepper-motor pinching mechanism that compresses or releases the system's compliant drain tubing in order to control the degree of CSF flow (i.e., equivalent to the alteration of CSF flow that happens when a traditional gravity drain is manually raised or lowered). The SED System displays the measured ICP information and also calculates and displays CSF flow volume output, while additionally incorporating multiple alarms given its automated functionality.

The SED System can thus automatically compensate for patient movement, allow greater mobility (via a battery backup) and also alert hospital staff if ever the ICP exceeds the set maximum or minimum levels for a particular patient, as well as if low or high CSF drainage values (as also set by the user) are ever exceeded.

The modifications included under this Special 510(k) include the following:

- Added ICP Waveform Display to User Interface Screen.
- Software loading via USB interface.
- Optimization of the SED System's initialization sequence.

Indications for Use: The Indications for Use statement for the subject device is identical to the predicate device, as follows:

Draining and monitoring of CSF flow from the lateral ventricles is indicated in selected patients to:

- Reduce intracranial pressure (ICP), e.g., pre-, intra- or postoperative.
- Monitor CSF chemistry, cytology, and physiology.
- Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts.

Monitoring of intracranial pressure (ICP) is indicated in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage graded III, IV, or V preoperatively

- Reye's syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Miscellaneous problems when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions.

Predicate Device: Aqueduct Critical Care, Inc. cites the following as the predicate device that is being modified.

Predicate Device	Smart External Drain (SED) System	K161605

Table 1 below provides a summary of the technological characteristics of the SED System in comparison to the predicate device.

Table 1: Comparative Summary of the Modified SED System and Predicate SED System

Detail or Technological Characteristic	Modified Aqueduct Critical Care, Inc. SED System	Predicate Aqueduct Critical Care, Inc. SED System (K161605)
Device Trade Name	Same	Smart External Drain (SED) System
Intended Use	Same	To attach to an implanted, external drainage catheter in order to externally drain cerebrospinal fluid (CSF) and monitor both CSF drainage and intracranial pressure (ICP)
Attaches to Separate, Commercially Available EVD Catheter	Same	Yes
Sterile Disposable Tubing Set	Same	Yes
CSF Drainage Bag	Same	Yes
Gravity Drainage of CSF	Same	Yes
Method to Control Gravity Drainage of CSF	Same	Automated adjustment based on user settings (for max/min ICP) via a stepper-motor controlled, tube-pinching mechanism to either compress or release the compliant drainage tubing contained within the sterile, disposable SED Cartridge.
Pressure Transducer for ICP Measurement	Same	Yes *(The SED System integrates transducers into its design for drain line and reference line pressure measurements that are used to calculate and regulate ICP.)*
Software-based, Powered Console for User Interface, User ICP and Alarm Setting Adjustments, Data Display, and Alarms for ICP Monitoring	Same (*The modified SED System now also incorporates an ICP waveform display.*)	Yes
Method to Account for Location of Ventricles via Patient Head Position	Same	Reference shroud attached to patient behind the ear (at the level of the External Auditory Meatus) to account for patient's head positioning.
Measured Pressure Range	Same	-5 to 40 cm H_2O (set ICP range)
Displayed ICP	Same	Yes *(via SED Console display)*
Battery Back-up	Same	Yes

Testing Summary: To demonstrate intended device performance, as well as to support the substantial equivalence of the modified SED System to the predicate SED System, the performance and technological characteristics were evaluated as summarized in Table 2 that follows.

Table 2: Summary Table for Modified SED System Testing

Testing	Testing Summary	Results/Conclusions
SED Cartridge Performance Testing		
SED Cartridge Button Verification	Modified SED Cartridges were tested to show that the modified manual pinch button location on the modified SED Cartridge met the following requirements: activation force, leak resistance, and fatigue life.	**PASS** – All acceptance criteria for the test method were met.
Drip Chamber Vent Verification	Modified SED Cartridges were tested to confirm that the vent activates as intended and that the vent does not leak (in its closed state) following exposure to the worst-case anticipated number of vent cycles.	**PASS –** All acceptance criteria for the test method were met.
Dimensional Verification	Modified SED Cartridges were weighed to confirm that the cartridge weight met the weight requirement.	**PASS** – All acceptance criteria for the test method were met.
Supplemental Verification	The only supplemental verification which required verification based on the modifications was size and weight, which were measured for the modified SED Cartridges.	**PASS** – All acceptance criteria for the test method were met.
Bond Joint Testing, SED Cartridge	Modified SED Cartridge subassemblies were used to destructively pull the 3 new bond joints.	**PASS** – All acceptance criteria for the test method were met.
SED System Performance Testing		
Functionality and Pressure Resistance Verification	The Modified SED System was tested to show that performance requirements were met for functionality, response time, and pressure and leak resistance, with the addition of fatigue cycling of the membrane assembly.	**PASS** – All acceptance criteria for the test method were met.
Verification of SED System Initialization Cycle	Testing of the modified software initialization cycle for the modified SED System was performed.	**PASS** – All acceptance criteria for the test method were met.
Verification of SED System Requirements	Testing was performed to verify the system-level performance of the SED System software modifications.	**PASS** – All acceptance criteria for the test method were met.
Verification of the Pressure Measurement Range of the SED System	The modified SED System was tested to the extremes of the pressure measurement range.	**PASS** – All acceptance criteria for the test method were met.
Software Testing		
Software Verification and Validation	Code verification and software verification and validation testing were performed on the modified software.	**PASS –** modified SED System met all acceptance criteria for verification and validation.

The results from these testing activities:

- demonstrate that the technological and performance characteristics of the modified SED System are comparable to the predicate SED System, and
- ensure the modified SED System can perform in a manner equivalent to the predicate SED System with the same intended use.

Conclusion (Statement of Equivalence): The information and summary of testing presented within this submission support a determination of substantial equivalence, and therefore market clearance of the modified SED System via this Special 510(k).