February 9, 2023

JMED(Shenzhen) Technology Limited
Anna Xiao
Regulatory Specialist
7#401, Zhongxing Road, Xiuxin Community,
Kengzi Street, Pingshan District
Shenzhen City, Guangdong 518122
China

Re: K221694
Trade/Device Name: External Drainage System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: January 10, 2023
Received: January 10, 2023

Dear Anna Xiao:

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: 2023.02.09 17:41:33 -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 *(if known)*
K221694

Device Name
External Drainage System

Indications for Use *(Describe)*
External Drainage System allows for drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP).

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

1 Submission Sponsor

JMED (Shenzhen) Technology Limited
7#401, Zhongxing Road No.14, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, Guangdong, 518122, P. R. China
Tel: 86-755-84513706
Email: registration@jmedtech.com.cn

2 Submission Correspondent

Anna Xiao
Regulatory Specialist
JMED(Shenzhen) Technology Limited
7#401, Zhongxing Road No.14, Xiuxin Community, Kengzi Street,Pingshan District, Shenzhen City, Guangdong, 518122, P. R. China
Tel: 86-755-84513706
Tel: 0086-13670075972
Email: yu.xiao@jmedtech.com.cn

3 Date Prepared

February 6, 2023

4 Device Identification

Trade Name: External Drainage System
Common Name: External Drainage System
Regulation Name: Central Nervous System Fluid Shunt and Components
Device Regulation: 21 CFR 882.5550
Device Classification: Class II
Product Code: JXG

5 Predicate Device

510(k) Number: K191684
Trade Name: MoniTorr ICP™ External CSF Drainage and Monitoring System; LimiTorr™ Volume Limiting External CSF Drainage and Monitoring System

6 Device Description

The External Drainage System includes a tubing, drainage bag, drip chamber and scale plate. It is provided sterile and can be connected to a drainage catheter, which is connected to a patient line, via a luer connection and ultimately to a drainage bag. The drainage catheter is not included in the subject device. The External Drainage System

provides a closed system for the drainage of cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space. During the draining, the cerebrospinal fluid will be collected in a drainage bag.

7 Indications For Use

External Drainage System allows for drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP).

8 Substantial Equivalence Discussion

Table 1 Comparisons between the subject device and the predicate device.

Table 1 General Comparison

Item	**Predicate Device** (K191684)	**Subject Device** (K221694)	**Comments**
	MoniTorr ICP™ External CSF Drainage and Monitoring System; LimiTorr™ Volume Limiting External CSF Drainage and Monitoring System	External Drainage System	
Indications for Use (IFU)	The MoniTorr ICP™ system allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected CSF shunts, and the monitoring of ICP. The LimiTorr™ system allows for drainage and monitoring of CSF from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF in patients with infected	External Drainage System allows for drainage of cerebral spinal fluid (CSF) from the lateral ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP)	Similar The IFU of the predicate device contains additional claims not applicable to the subject device.
	Predicate Device (K191684)	**Subject Device** (K221694)	

Item	MoniTorr ICP™ External CSF Drainage and Monitoring System; LimiTorr™ Volume Limiting External CSF Drainage and Monitoring System	External Drainage System	Comments
	CSF shunts, and to monitor ICP.		
Sterility Information	Provide sterile, single use. EO Sterilized with sterility assurance level (SAL) is 10^{-6}	Provide sterile, single use, EO Sterilized with sterility assurance level (SAL) is 10^{-6}	Identical
Device Components	LimiTorr Volume Liming External CSF Drainage and Monitoring System: Tubing (Patient line with green strip, stopcock, needleless sampling site). Drainage bag with an anti-reflux valve, needleless sampling site). Graduated burette (Antimicrobial hydrophobic vent, burette stopcock and blue cap). MoniTorr ICP External CSF Drainage and Monitoring System: Tuning (patient line with green strip, stopcocks, red end cap, injection site). Drainage bag with injection site and anti-reflux valve. Graduated chamber, microbial filter vent, drip former, pressure level, chamber stopcock, panel and injection site. Pole mount bracket assembly with clamping screw.	Patient connection Tubing (3-way stopcock with injection port & sample port, male luer connector, anti-reflux valve, stopcock, female luer connector, drip pot). Drainage bag (2-way stopcock, hydrophobic membrane, cord, cord lock). Drip chamber with scale plate, 3-way stopcock and tubing.	Similar The main device components are similar

Item	Predicate Device (K191684)	Subject Device (K221694)	Comments
	MoniTorr ICP™ External CSF Drainage and Monitoring System; LimiTorr™ Volume Limiting External CSF Drainage and Monitoring System	External Drainage System	
Device Materials	The patient line, stopcock, graduated burette and anti-reflux valve may come in indirect contact with the patient: (1) Patient line: Not available (2) Stopcock: HDPE and polycarbonate (3)Graduated burette: Not available (4) Anti-reflux valve: Not available	The tubing ,3-way stopcock, male luer connector and anti-reflux valve may come in indirect contact with the patient: (1) Tubing: PVC (2) 3-way stopcock: PC (3) Male luer connector: PC (4) Anti-reflux valve: PC	Similar

The subject and predicate devices have similar intended use, sterilization method and device components. The differences among the devices do not impact the performance of the subject device.

9 Summary of Non-Clinical Performance Testing

The following test were performed to verify that the performance of the subject device is substantially equivalent to the performance of the predicate device. Testing included side-by-side comparison data with the predicate device.
Please see the Summary of Testing Table 2 below for test results.

Table 2 Performance Bench Test Results

Test Item	Test Methods	Results
Device size requirements	To determine if the size of the device components is within specifications.	Pass
Fluid leakage by pressure decay test	To establish that the tubing meets fluid leakage specifications.	Pass
The volume and scale of the drip chamber	To determine if the volume and scale of the drip chamber is within current specifications.	Pass
Integrity of air vent filter of the drip chamber	To determine if the integrity of air vent filter of drip chamber is within current specifications.	Pass

Integrity of air vent filter of the drainage bag	To determine if the integrity of air vent filter of drainage bag is within current specifications.	Pass
Packaging integrity	To determine if the packaging integrity is within current specifications.	Pass
Package sealing strength	To determine if the sealing strength of the package is within current specifications.	Pass
Sterility	To determine if the sterility of the device is within current specifications for ethylene oxide.	Pass
Endotoxin testing	To determine if the endotoxin of the device is within specifications of 2.15 EU/device.	Pass

The External Drainage System is categorized as an externally communicating device in prolonged contact (>24 hour to 30 days) with CSF and indirect blood contact. The following test were completed in accordance with FDA biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."

Table 3 Biocompatibility Test Summary

Test item	Results	Conclusions
In vitro Cytotoxicity Test	Test article extracts showed no evidence of cytotoxicity.	Non-cytotoxic
Skin sensitization tests	Test article extracts showed no evidence of causing skin sensitization in the guinea pig.	Non-sensitizing
Intracutaneous reactivity test	The test article extracts showed no evidence of intracutaneous reactivity in rabbit.	Non-irritant
Acute systemic toxicity test	The test article extracts showed no evidence of acute systemic toxicity. - No mortality during the study - All animals were clinically normal throughout the study - Body weight data were acceptable	Non-toxic acutely
Material mediated pyrogenicity test	The test article met the requirements for the absence of pyrogens.	Non-pyrogenic

In vitro hemolysis study	Under the conditions of this study, the hemolytic index of test article was 0.8%.	Non-hemolytic

5.10 Conclusion

The subject and predicate devices have similar indications for use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions on safety and effectiveness. The non-clinical performance data demonstrates that the subject device is substantially equivalent to the predicate device.