October 24, 2024

Medtronic Neurosurgery
Sudeep Nambiar
Senior Regulatory Affairs Manager
4620 N. Beach Street
Fort Worth, Texas 76137

Re: K242034
Trade/Device Name: Duet External Drainage and Monitoring System (EDMS)
Regulation Number: 21 CFR 882.5560
Regulation Name: Cerebrospinal Fluid Shunt System
Regulatory Class: Class II
Product Code: PCB
Dated: July 11, 2024
Received: September 27, 2024

Dear Sudeep Nambiar:

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 quality systems (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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.10.24 16:52:53 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242034

Device Name
Duet External Drainage and Monitoring System (EDMS)

Indications for Use *(Describe)*
The DUET EDMS is indicated for temporary draining and monitoring of cerebrospinal fluid (CSF) flow from the lumbar subarachnoid space in:
1. Patients undergoing open descending thoracic aortic aneurysm (open TAA) or open descending thoraco-abdominal aortic aneurysm (open TAAA) repair surgery.
2. Patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Medtronic

510(k) Summary

I. Company: Medtronic Neurosurgery
4620 N Beach Street,
Fort Worth, Texas 79137 USA

Contact: Foram Shukla
Regulatory Affairs Specialist
foram.a.shukla@medtronic.com
Telephone Number: 817-788-6400

Alternate Contact: Rishi Sinha
Senior Regulatory Affairs Director
rishi.k.sinha@medtronic.com
Telephone Number: 720-890-2485

II. Proprietary Trade Name: Duet External Drainage and Monitoring System (EDMS)

III. Regulatory Class: II

IV. Primary Classification:

Name: Cerebrospinal Fluid Shunt System
Product Code: PCB
Regulation: 21 CFR 882.5560

V. Identification of Legally Marketed Predicate Devices

Primary Predicate device: Duet External Drainage and Monitoring (DEN120017)
Reference device: Exacta External Drainage and Monitoring System (K201118)

VI. Product Description

The Medtronic Duet External Drainage and Monitoring System (Duet EDMS) is a complete system for externally draining and monitoring cerebrospinal fluid (CSF) and monitoring intracranial pressure (ICP). It can be used for both external ventricular and lumbar drainage. The Duet™ EDMS is an external drainage and monitoring system that uses gravity to drain cerebrospinal fluid (CSF) from the patient's ventricles or lumbar space to an external drainage

Medtronic

receptacle. The drainage flow of CSF into the Duet EDMS is uni-directional and gravity-driven; there is no recirculation of the CSF. The Duet's catheter is surgically attached to the patient before it is attached to the drainage system. An opening is made in the patient's skull or lumbar region and a catheter is inserted into patient's ventricle or the lumbar subarachnoid space. The catheter is then attached to the drainage system. The CSF or blood is drained and monitored until the patient is stabilized, the infection successfully treated, or a long-term drainage method is implemented.

VII. Indications for Use

The DUET EDMS is indicated for temporary draining and monitoring of cerebrospinal fluid (CSF) flow from the lumbar subarachnoid space in:

1. Patients undergoing open descending thoracic aortic aneurysm (open TAA) or open descending thoraco-abdominal aortic aneurysm (open TAAA) repair surgery;
2. Patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia.

VIII. Summary of the Technological Characteristics

The subject device and the predicate device have the same indications for use, intended use, fundamental technology and operating principle. The only difference between the subject device and the predicate is in the patient line tubing material. The patient line tubing of the subject device Duet EDMS is same as the reference device, Exacta EDMS that was cleared under K201118.

IX. Device Comparison

The tables below provide a summary of the device.

Table 1: Subject to Predicate Device Comparison – Technological Characteristics

Characteristic	Subject Device	Predicate Device
Device Name	Duet External Drainage and Monitoring	Duet External Drainage and Monitoring
510k Number	K242034	DEN120017
Indications for Use	The DUET™ EDMS is indicated for temporary draining and monitoring of cerebrospinal fluid (CSF) flow from the lumbar subarachnoid space in: 1. Patients undergoing open descending thoracic aortic	The DUET™ EDMS is indicated for temporary draining and monitoring of cerebrospinal fluid (CSF) flow from the lumbar subarachnoid space in: 1. Patients undergoing open descending thoracic aortic

Characteristic	Subject Device	Predicate Device
	aneurysm (open TAA) or open descending thoraco-abdominal aortic aneurysm (open TAAA) repair surgery; 2. Patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia.	aneurysm (open TAA) or open descending thoraco-abdominal aortic aneurysm (open TAAA) repair surgery; 2. Patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia.
Patient Line Tubing	Visible Identification: Green stripe downside of tubing to indicate drainage line.	Same
Drip Chamber Assembly	• Sliding, graduated 75 ml flow chamber with drip former, tapered bottom, and locking bracket. • "Window" frames desired pressure setting. .	• Sliding, graduated 75 ml flow chamber with drip former, tapered bottom, and locking bracket. • "Window" frames desired pressure setting.
Pressure Scales	• Unit of Measure: cmH_2O and mmHg • Location: 4-way rotating pole scale attached to panel • Scale markings are placed onto Rotating Scale Tube – one pressure scale showing per ¼ rotation	• Unit of Measure: cmH_2O and mmHg • Location: 4-way rotating pole scale attached to panel • Scale markings are placed onto Rotating Scale Tube – one pressure scale showing per ¼ rotation

Characteristic	Subject Device	Predicate Device
Height Adjustment Cord	Self-adjusting cord with locking mechanism to adjust height of drainage system.	Self-adjusting cord with locking mechanism to adjust height of drainage system.
Dimensions	Outer diameter: 0.124 inches Inner diameter: 0.075 inches	Same
Device Accessories	• ClearSite Laser Levels • Replacement Drainage Bag for the Duet External Drainage and Monitoring System	• ClearSite Laser Levels • Replacement Drainage Bag for the Duet External Drainage and Monitoring System
Biocompatibility - Patient contact and duration	Prolonged contact (>24hrs to 30 days) external communicating device with indirect contact with blood path.	Same
Shelf-life	3 years	3 years
Sterilization method	Ethylene Oxide	Same

X. Discussion of the Performance Testing

In accordance with the risk assessment of the change it was determined that dimensional verification, and design verification testing of the patient line tubing was necessary. Based on the Design Verification assessment, change in Duet EDMS patient line tubing impacts the requirements mentioned in Table 2. The performance testing mentioned in Table 2 was completed to evaluate a change to the patient line tubing. The successful results of the testing mentioned in Table 2 demonstrated that the change in patient line tubing establishes safety and effectiveness, supporting the substantial equivalence to the predicate device. The performance testing and special controls summarized in DEN120017 are applicable to the subject 510(k) and support safe use of the subject device.

Table 2: Performance Testing

Test Name	Test Method	Results
Leakage of UV Cure Bonds	The UV-cure bonds between the patient line and drip chamber subassembly should withstand air pressure without causing leaks.	Pass
Attachment of Junctions	Junctions must be able to withstand minimum of 5-pound load in the axial direction.	Pass

XI. Biocompatibility Testing

Biocompatibility assessment was conducted based on Appendix A of the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. The Duet EDMS (including the patient line tubing) is categorized as a prolonged (>24h to 30 d) external communicating device with indirect blood path contact. The patient line tubing material change does not raise biocompatibility concerns for the following endpoints: cytotoxicity, sensitization, irritation, pyrogenicity, acute systemic toxicity, subacute/subchronic toxicity and hemocompatibility.

XII. Conclusion

The information provided in this submission demonstrates that the subject device Duet EDMS has the same intended use as the predicate device. The differences in technological characteristics introduced by the proposed changes to the patient line tubing do not alter the intended use of the subject device and do not raise different questions of safety or effectiveness. Based on the information provided in this submission and the performance testing, the subject device Duet EDMS is considered substantially equivalent to the cleared predicate device Duet EDMS (DEN120017).