March 10, 2025

Medtronic Neurosurgery
Foram Shukla
Regulatory Affairs Specialist
4620 N. Beach Street
Fort Worth, Texas 76137

Re: K243676
Trade/Device Name: Duet External Drainage and Monitoring System (EDMS)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 27, 2024
Received: February 6, 2025

Dear Foram Shukla:

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: 2025.03.10 13:56:42 -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)*
K243676

Device Name
Duet External Drainage and Monitoring System (EDMS)

Indications for Use *(Describe)*

The Duet EDMS is indicated for draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space 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
• Reyes 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

March 7, 2025

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

Contact: Foram Shukla
Regulatory Affairs Specialist
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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: Central nervous system fluid shunt and components
Regulation: 21 CFR 882.5550
Classification Product Code: JXG

V. Identification of Legally Marketed Predicate and Reference Devices

Predicate device: Becker External Drainage and Monitoring System (K200456)
Reference device: Duet™ External Drainage and Monitoring System (K242034)

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 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 draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space 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
- Reyes 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.

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.

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 System	Becker External Drainage and Monitoring System
Classification Procode	JXG	GWM

Characteristic	Subject Device	Predicate Device
510k Number	K243676	K200456
Intended Use	Draining and monitoring cerebrospinal fluid (CSF) and monitoring intracranial pressure (ICP).	Same
Indications for Use	The Duet™ EDMS is indicated for draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space 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 CSF shunts. Monitoring of intracranial pressure (ICP) is indicated in selected patients with: • Severe head injury • Subarachnoid hemorrhage graded III, IV, or V preoperatively • Reyes 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.	Draining and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space 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 CSF shunts. Monitoring of intracranial pressure (ICP) is indicated in selected patients with: • Severe head injury • Subarachnoid hemorrhage graded III, IV, or V preoperatively • Reyes 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.

Characteristic	Subject Device	Predicate Device
Principle of Operation	External drainage is temporary drainage of cerebrospinal fluid (CSF) from the lateral ventricles of the brain, or the lumbar space of the spine, into an external collection bag. The Duet™ EDMS drains CSF by using a combination of gravity and intercerebral pressure. The drainage rate depends on the height at which the system is placed relative to the patient's anatomy.	Same
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 50 ml flow chamber with drip former and conical bottom and locking bracket. • Pressure scale underlines desired pressure setting.
Pressure Scales	• Unit of Measure: cmH2O 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: cmH2O and mmHg • Location: Printed directly onto scale • Scales are side by side
Height Adjustment Cord	Self-adjusting cord with locking mechanism to adjust height of drainage system.	Same
Device Accessories	• ClearSite Laser Levels • Replacement Drainage Bag.	• Replacement Laser Level • Becker Quick-Attach Pole Clamp with Laser Level • Becker Quick-Attach Pole Clamp (without Laser Level) • Replacement Drainage Bag.

Characteristic	Subject Device	Predicate Device
Biocompatibility - Patient contact and duration	Prolonged (>24hrs - <30 days) external communicating device with blood path	Same
Shelf-life	3 years	2 years
MRI Safety Information	MR Conditional	MR Unsafe
Sterilization method	Ethylene Oxide	Same

X. Discussion of the Performance Testing

"Testing demonstrated the performance of the device for its intended use. The performance testing summarized in Table-2 has been conducted in support of the substantial equivalence determination for the proposed change. Results of verification and validation testing conducted on the Duet EDMS demonstrated that the subject device performed as designed, is suitable for its intended use and is substantially equivalent to the predicate device." The subject device is also identical to the reference device Duet™ External Drainage and Monitoring System (K242034).

Table-2: Performance Testing of Duet EDMS

Test Name	Test Method Summary	Results
Dimensional	Measure the dimensions of the scale label vertical and horizontal alignment, pressure scale lengths, patient line tubing inner diameter (ID) and length, cord length, drainage path ID (from bottom of drip chamber), and stopcock flow path diameter.	Pass
Drip Chamber Graduations	Verify the correct readings on the drip chamber graduation.	Pass
Main System Stopcock (MSS) Assembly Torque Applied to Arm of Stopcock	Record the peak torque at which the MSS assembly fails or detaches from the panel.	Pass
MSS Assembly Load Applied to Core of Stopcock Arm	Record peak load at which MSS assembly failed.	Pass

Test Name	Test Method Summary	Results
Clamp to I.V. Pole Attachment Strength	Ensure secure attachment of clamp to I.V. pole.	Pass
Cord to I.V. Pole Attachment Strength	Ensure cord and cord lock maintains secure hanging of system.	Pass
Drip Chamber to Back Panel Attachment Strength	Ensure secure attachment of drip chamber/bag subassembly to panel.	Pass
Strength of Attached Junctions (Tubing to Luer)	Ensure secure attachment of junctions of tubes to luer.	Pass
Bottom Cap to Stopcock Junction Torque	Ensure secure bond of stopcock/bottom cap.	Pass
Drip Assembly and Drainage Bag Vent Integrity	Ensure that drip assembly and drainage bag vent can withstand appropriate fluid pressures.	Pass
Tensile Strength of Drainage Bag Inlet Port	Evaluate the tensile strength of the drainage bag inlet port to failure.	Pass
Drainage Bag Seal Weld	Ensure there are no leaks in the drainage bag.	Pass
Flow Initiation Pressure	Record pressure at which flow initiates, for each drainage bag.	Pass
Drip Assembly Vent Test (Exposure of Vent to Blood Solution)	Ensure that the drip assembly vent allows drainage of blood and provide CSF flow through system with minimal resistance.	Pass
Drip Assembly Vent Integrity	Test the drip assembly vent to withdraw fluid without compromising its mechanical integrity.	Pass
Leakage of UV-Cure Bonds	Record any leakage from the UV-cure bonds between the patient line and drip chamber subassembly.	Pass
Leakage of Drainage Bag	The drainage bag must withstand being inverted without leaking.	Pass
Drip Chamber Volume	Verify fluid weight in the drip chamber.	Pass

Test Name	Test Method Summary	Results
Attachment of I.V. Pole and Position of Adjustable Drip Chamber	Visually verify that clamping thumbscrews (and cord locks) have not slipped from initial positions (using visual marks to identify any slippage).	Pass
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
Bottom Cap to Stopcock Junction Torque	Test the torque of the stopcock/bottom cap bond.	Pass
Hydrophobic Microbial Barrier Vent on the Drainage Bag	The supplier for the material used as the drainage bag vents conducted microbial barrier testing to demonstrate a 99.9% Bacterial Filtration Efficiency (BFE).	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 is categorized as a prolonged (>24h to 30 d) external communicating device with indirect blood path contact. The biocompatibility evaluation for the cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, subacute/subchronic toxicity, and indirect hemolysis endpoints was completed in accordance with FDA’s biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"".

XII. Conclusion

The information provided in this submission demonstrates that the subject device Duet™ EDMS has the same intended use as the predicate devices. Based on the similarities of the device design, principles of operation, technological characteristics and results of the non-clinical performance testing, the subject device Duet™ EDMS is substantially equivalent to the cleared predicate device Becker External Drainage and Monitoring System (K200456).