



April 9, 2020

Medtronic, Inc.
Jen Correa
Manager, Regulatory Affairs
5290 California Avenue
Irvine, California 92617

Re: K200630

Trade/Device Name: Medtronic External Drainage and Monitoring System (EDMS)

Regulation Number: 21 CFR 882.1620

Regulation Name: Intracranial Pressure Monitoring Device

Regulatory Class: Class II

Product Code: GWM, HCA

Dated: March 9, 2020

Received: March 10, 2020

Dear Jen Correa:

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,

Xiaolin Zheng, Ph.D., M.S.
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

Indications for Use

510(k) Number (if known)

K200630

Device Name

Medtronic External Drainage and Monitoring System (EDMS)

Indications for Use (Describe)

Draining CSF and monitoring CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

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

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with:

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

Monitoring can also be used to evaluate the status pre- and postoperative 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.

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510(k) Summary

Medtronic External Drainage and Monitoring System (EDMS)

510(k) Summary

April 6, 2020

- I. Company:** Medtronic Neurosurgery
5290 California Ave
Irvine, CA 92617 USA
- Contact:** Jen Correa
Manager, Regulatory Affairs
Jennifer.L.Correa@medtronic.com
Telephone Number: 949-297-5494
- II. Establishment Registration Number:** 3015531529
- III. Proprietary Trade Name:** Medtronic External Drainage and Monitoring System (EDMS)
- IV. Regulatory Class:** II
- V. Primary Classification**
Name: Intracranial pressure monitoring device
Product Code: GWM
Regulation: 21 CFR 882.1620
- Secondary Classification:**
Name: Ventricular catheter
Product Code: HCA
Regulation: 21 CFR 882.4100
- VI. Product Description:** The Medtronic External Drainage and Monitoring System EDMS is provided as a complete closed system for the drainage and monitoring of cerebrospinal fluid (CSF) flow from the lateral ventricles or the lumbar subarachnoid space. The system is offered in various kit configurations for various clinical applications. The EDMS Drainage Assembly is supplied pre-assembled, sterile and non-pyrogenic in a double wrap package system. A drainage bag with braided cord is also included with each EDMS kit.
- The EDMS and components are intended for single (one time) use only and is not designed or intended to be re-used, re-processed, or re-sterilized. Some of the basic features include the following:
- a patient line stopcock with latex-free injection site and non-distensible patient connection line;
 - a graduated chamber and hanging bracket for I.V. pole suspension;
 - a drainage bag connection line with two slide clamps and latex-free injection site;

- a removable vented drainage bag with approximate volumetric graduations and drainage port;
- pressure scale tape.

VII. Indications for Use:

Draining CSF and monitoring CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:

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

The monitoring of the intracranial pressure (ICP) is indicated in selected patients with:

1. Severe head injury
2. Subarachnoid hemorrhage graded III, IV or V preoperatively
3. Reye’s syndrome or similar encephalopathies
4. Hydrocephalus
5. Intracranial hemorrhage
6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.

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

VIII. Summary of the Technological Characteristics: The proposed subject drainage bag shares the same technological characteristics as the original predicate drainage bag. The rest of the EDMS device has the same technological characteristics as the predicate device.

	Subject Device	Predicate Device K802100
Intended use/Indications for Use	<p>Draining CSF and monitoring CSF flow from the lateral ventricles or lumbar subarachnoid space is indicated in selected patients to:</p> <ol style="list-style-type: none"> 1. Reduce intracranial pressure (ICP), e.g. pre-, intra- or postoperative. 2. Monitor CSF chemistry, cytology and physiology. 3. Provide temporary CSF drainage in patients with infected cerebrospinal fluid shunts. <p>The monitoring of the intracranial pressure (ICP) is indicated in selected patients with:</p> <ol style="list-style-type: none"> 1. Severe head injury 	<p>The monitoring of intracranial pressure (ICP) is indicated on selected patients with:</p> <ol style="list-style-type: none"> 1. Severe head injury. 2. Status pre- and postoperative for space-occupying intracranial lesions. 3. Subarachnoid hemorrhage graded IV or V preoperatively. 4. Reyes syndrome or similar encephalopathies. 5. Hydrocephalus. 6. Intracranial hemorrhage. 7. Miscellaneous problems when ventricular drainage is to be used as a therapeutic maneuver.

	Subject Device	Predicate Device K802100
	<p>2. Subarachnoid hemorrhage graded III, IV or V preoperatively</p> <p>3. Reye’s syndrome or similar encephalopathies</p> <p>4. Hydrocephalus</p> <p>5. Intracranial hemorrhage</p> <p>6. Miscellaneous problems when drainage is to be used as a therapeutic maneuver.</p> <p>Monitoring can also be used to evaluate the status pre- and postoperative for space-occupying lesions.</p>	
Operating Principle	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 Medtronic EDMS drains CSF by using a combination of gravity and intracerebral pressure. The drainage rate depends on the height at which the system is placed relative to the patient’s anatomy.	Same
Anatomical Sites	Drainage and monitoring of CSF flow from the lateral ventricles or lumbar subarachnoid space.	Same
Biocompatibility	No direct patient contact In contact with CSF only	Same
Sterilization Method	Ethylene Oxide	Same
Pyrogenicity	Non pyrogenic	Same
Shelf life	2 yr.	Same

IX. Identification of Legally Marketing Devices: The Intracranial Pressure Monitoring System, Becker Design, K802100.

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 bag was necessary. The successful results of the testing demonstrated that the changes do not raise questions of safety and effectiveness, supporting the substantial equivalence to the predicate device.

Performance Data – Bench

Test	Test Method Summary / Purpose	Results
Visual and Dimensional Inspection	Visual and dimensional inspection demonstrates that the printed graduations meet volumetric capacity. Volumetric graduations are approximate.	The EDMS device met the acceptance criteria for visual and dimensional inspection.
Leakage of Drainage Bag	The drainage bag must withstand being inverted without leaking.	The EDMS device met the acceptance criteria for drainage bag leakage.
Flow Initiation Pressure	Record pressure at which flow initiates, for each drainage bag.	The EDMS device met the acceptance criteria for flow initiation pressure.
Drainage Bag Seal Weld	Ensure there are no leaks in the drainage bag.	The EDMS device met the acceptance criteria for drainage bag seal weld.
Tensile Strength of Drainage Bag Inlet Port	Evaluate the tensile strength of the drainage bag inlet port to failure.	The EDMS device met the acceptance criteria for tensile strength of drainage bag inlet port.

Performance Data – Animal

The risk assessment of the proposed modifications to the disposable bag did not require animal testing. Determination of substantial equivalence for the design change is based upon the design verification bench testing.

Performance Data – Clinical

The risk assessment of the proposed modifications to the disposable bag did not require clinical testing. Determination of substantial equivalence for the design change is based upon the design verification bench testing.

- XI. Conclusions:** The information provided in this submission demonstrates that the subject device, the Medtronic EDMS, has the same intended use/indications for use as the predicate device and the differences in technological characteristics introduced by the proposed changes to the drainage bag do not raise any questions of safety and effectiveness. Based on the information provided in this submission the subject Medtronic EDMS device is considered substantially equivalent to the previously cleared predicate device.