March 26, 2020

Medtronic, Inc.
Nancy Hampton, Ph.D.
Principal Regulatory Affairs Specialist
125 Cremona Drive
Goleta, California 93117

Re: K200456
Trade/Device Name: Becker External Drainage and Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM, HCA
Dated: February 20, 2020
Received: February 25, 2020

Dear Dr. Nancy Hampton:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200456

Device Name
Becker External Drainage and Monitoring System

Indications for Use *(Describe)*

Draining and monitoring of 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.

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

1. Severe head injury
2. Subarachnoid hemorrhage graded III, IV, or V preoperatively
3. Reyes 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 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.

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510(k) Summary

Becker® External Drainage and Monitoring System

510(k) Summary

March 26, 2020

I. Company:

Medtronic, Inc.
Medtronic Neurosurgery
125 Cremona Drive
Goleta, California 93117 USA

Contact: Nancy Hampton, PhD
Principal Regulatory Affairs Specialist
nancy.d.hampton@medtronic.com
Telephone Number: 949-490-3773

II. Establishment Registration Number: 2021898

III. Proprietary Trade Name: Becker® External Drainage and Monitoring System

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 Becker External Drainage and Monitoring System (Becker EDMS) provides the physician with a complete closed system for:

1. Draining cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space.

2. Monitoring CSF pressure and flow rate from the lateral ventricles of the brain and the lumbar subarachnoid space.

The Becker EDMS consists of a nondistensible blue or green striped (proximal end) patient connection line, patient line stopcock, mounting panel/main system section, two latex-free injection sites and a removable drainage bag with approximate volumetric graduations and microbial barrier air vent.

The main system section located on the mounting panel includes:

1. Mounting bracket for height adjustment of system
2. Optional self-adjusting cord with lock for adjustment of system height
3. Main system stopcock with optional transducer attachment location
4. Sliding, graduated, 50 cc drip chamber with drip former and conical bottom, and locking bracket
5. Two drainage line slide clamps for flow monitoring and sampling
6. Drainage bag connection line
7. Needleless Injection Site (Interlink or Smartsite)
8. Instructions for Use

The system does not contain any latex components.

VII. Indications for Use:

Draining and monitoring of 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.

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

1. Severe head injury
2. Subarachnoid hemorrhage graded III, IV, or V preoperatively
3. Reyes 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 postoperatively for space-occupying lesions.

VIII. Summary of the Technological Characteristics:

The proposed Becker EDMS modified disposable bag is a sterile nonpyrogenic single use component of the system that is removable from the Becker EDMS mounting panel. The bag has an approximate volume capacity of 600ml with approximate volumetric markings in 50mL increments, an inlet port, an outlet port and a hydrophobic/anti-microbial vent embedded into the body of the bag. The rest of the Becker EDMS system has the same technological characteristics as the predicate device.

	Subject Device	Predicate Device K984053
Intended use / Indications for Use	Draining and monitoring of 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. Monitoring of intracranial pressure (ICP) is indicated in selected patients with: 1. Severe head injury 2. Subarachnoid hemorrhage graded III, IV, or V preoperatively 3. Reyes 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 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 cerebrospinal fluid shunts. The monitoring of the 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 or 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.
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 Becker 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
Materials	There are no materials with direct patient contact	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	Same

	Subject Device	Predicate Device K984053
Sterilization Method	Ethylene Oxide	Same
Pyrogenicity	Non pyrogenic	Same
Shelf life	2 years	Same

IX. Identification of Legally Marketing Predicate Devices: Medtronic PS Medical Becker External Drainage and Monitoring System, K984053.

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 Becker 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 Becker EDMS device met the acceptance criteria for drainage bag leakage.
Flow Initiation Pressure	Record pressure at which flow initiates, for each drainage bag.	The Becker EDMS device met the acceptance criteria for flow initiation pressure.
Drainage Bag Seal Weld	Ensure there are no leaks in the drainage bag.	The Becker 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 Becker 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 Becker 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 disposable bag do not raise questions of safety and effectiveness. Based on the information provided in this submission the subject Becker EDMS device is considered substantially equivalent to the previously cleared predicate device.