May 26, 2020

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

Re: K201118
Device Name: Exacta 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: April 24, 2020
Received: April 27, 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 -S

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

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)*
K201118

Device Name
Exacta External Drainage and Monitoring System (EDMS)

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 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 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.

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."

510(k) Summary

Medtronic Exacta External Drainage and Monitoring System (EDMS)

510(k) Summary

May 19, 2020

I. Company: Medtronic Neurosurgery
5290 California Ave
Irvine, CA 92617 USA

Contact: Jen Correa
Program Manager, Regulatory Affairs
Jennifer.L.Correa@medtronic.com
Telephone Number: 949-297-5494

II. Establishment Registration Number: 3015531529

III. Proprietary Trade Name: Exacta External Drainage and Monitoring System (EDMS)

IV. Regulator Classification: 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 Exacta 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 Exacta EDMS product family is comprised of a single use drainage system, a reusable blue pole clamp and a laser level accessory. The single use drainage assembly is comprised of a patient line, main system stopcock, graduated cylinder and drainage bag. The single use drainage assembly is mounted on the reusable blue pole clamp. The reusable blue pole clamp secures the system to an I.V. pole and includes the system pressure scale and holds an optional laser level accessory. The optional laser level accessory assists the user in leveling the single use drainage system to the patient's Foramen of Monro or lumbar catheter exit site.

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 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 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 subject laser level device shares the same features and use as the predicate laser level. The rest of the Exacta EDMS device has the same technological characteristics as the predicate device.

	Subject Device	**Predicate Device K983799**
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 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 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.	Same

	Subject Device	Predicate Device K983799
	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.	
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 Exacta 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
Materials	There are no materials with direct patient contact	Same
Laser Level Accessory Features and Use	Battery-operated reusable non-sterile accessory that is used to align the external reference point with the zero reference point of the EDMS device.	Same
Laser Level Accessory Design	Level Bubbles: Two, located at top and bottom of device Maximum Output: <5.0 mW Wavelength: 650nm Laser Classification: 3R	Level Bubbles: Same Maximum Output: <1 mW Wavelength: 670nm Laser Classification: 2
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: Medtronic PS Medical Niveau Drainage System, K983799.

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 laser level was necessary. As the changes to the laser level design potentially impact EMC and electrical safety, the design verification testing was completed to demonstrate compliance to the following electrical standards:

- IEC 60601-1:2005 + AMD1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 / EN 60601-1-2:2015, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

In addition, laser testing was completed in compliance with IEC/EN 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements.

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**
Mechanical Strength	Verify laser does not present a safety hazard after push test, impact test and dropping.	The laser level device met the acceptance criteria for mechanical strength.
Beam Uniformity	Measure and record the beam uniformity to determine offset	The laser level device met the acceptance criteria for beam uniformity
Laser Accuracy	Calculate and record the laser accuracy at a set distance	The laser level device met the acceptance criteria for laser accuracy
Laser Safety	Verify laser power output complies with exposure limits for Class 3R Laser	The laser level device met the acceptance criteria for laser safety
Auto Shut Off	Measure and record the time laser is “on” after activation	The laser level device met the acceptance criteria for auto shut off

Performance Data – Animal

The risk assessment of the proposed modifications to the laser level 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 laser level 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 Exacta 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 laser level device do not raise any questions of safety and effectiveness. Based on the information provided in this submission the subject Exacta EDMS device is considered substantially equivalent to the previously cleared predicate device.