



Food and Drug Administration
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November 6, 2018

Medtronic Neurosurgery
Mr. Donovan May
Senior Regulatory Affairs Specialist
125 Cremona Drive
Goleta, CA 93117

Re: DEN120017 (K122087)
Medtronic DUET™ External Drainage and Monitoring System (EDMS)
Evaluation of Automatic Class III Designation – De Novo Request
Regulation Number: 21 CFR 882.5560
Regulation Name: Cerebrospinal fluid shunt system
Regulatory Classification: Class II
Product Code: PCB
Dated: December 19, 2012
Received: December 21, 2012

Dear Mr. May:

This letter corrects our classification order dated August 22, 2014.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Medtronic DUET™ External Drainage and Monitoring System (EDMS), a prescription device under 21 CFR Part 801.109 that 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, and 2) patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Medtronic DUET EDMS, and substantially equivalent devices of this generic type, into class II under the generic name, cerebrospinal fluid shunt system.

FDA identifies this generic type of device as:

Cerebrospinal fluid shunt system. A cerebrospinal fluid shunt system is a prescription device used to monitor and divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of preventing spinal cord ischemia or injury during procedures that require reduction in central nervous system pressure. A cerebrospinal fluid shunt system may include catheters, valved catheters, valves, connectors, and pressure monitors intended to facilitate use of the shunt or evaluation of a patient with a shunt.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 27, 2012 automatically classifying the Medtronic DUET™ EDMS in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On December 21, 2012, FDA received your De Novo requesting classification of the Medtronic DUET™ EDMS into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Medtronic DUET™ EDMS into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the De Novo request, FDA has determined that the Medtronic DUET™ EDMS 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, and 2) patients post TAA/TAAA repair that become symptomatic with neurological deficit such as paraplegia can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Pyrogenicity/adverse tissue reaction	Biocompatibility testing Pyrogenicity testing Labeling Shelf-life testing Sterility testing
Infection (including meningitis)	Labeling Sterility testing Package integrity testing
Cerebrospinal fluid (CSF) leakage	Labeling

Identified Risk	Mitigation Measure
	Non-clinical performance testing
Over - & under-drainage <ul style="list-style-type: none"> • Spinal headache with and without CSF leakage • Intracranial hemorrhage • Hematoma (e.g., spinal, subdural) • Paraplegia • Foreign body obstruction 	Labeling Non-clinical performance testing
Procedural/use errors	Labeling

In combination with the general controls of the FD&C Act, the cerebrospinal fluid shunt system is subject to the following special controls:

1. The device description must include a detailed summary of the device technical parameters, including design configuration, dimensions, engineering drawings, and a list of all components with identification of their materials of construction.
2. The patient-contacting components of the device must be demonstrated to be biocompatible.
3. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
 - a. Simulated use testing must be conducted to characterize fluid flow and resistance to leakage.
 - b. Mechanical integrity testing of all connections must be conducted.
4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf life.
5. Performance data must demonstrate the sterility and pyrogenicity of patient-contacting components of the device.
6. The labeling must include:
 - a. Contraindications with respect to patients who should not receive a lumbar drain;
 - b. A warning that the device should have 24-hour-a-day availability of trained personnel to supervise monitoring and drainage;
 - c. Instructions on proper device set-up, positioning and monitoring;
 - d. Warnings and precautions to inform the user of serious hazards and special care associated with the use of the device;
 - e. A statement that the device is not to be reused, reprocessed, or resterilized when open but unused; and
 - f. Cleaning instructions for the injection sites.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification

is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the cerebrospinal fluid shunt system they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Xiaolin Zheng, Ph.D. at (301) 796-2823.

Sincerely yours,

Angela C. Krueger
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health