October 1, 2018

Medtronic Neurosurgery
Xiaojian Sun
Regulatory Affairs Manager
125 Cremona Drive
Goleta, California 93117

Re: K181622
Trade/Device Name: StrataMR Valves and Shunts (Guider Tool)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: July 2, 2018
Received: July 3, 2018

Dear Xiaojian Sun:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K181622

Device Name
StrataMR™ Valves and Shunts (Guider Tool)

Indications for Use *(Describe)*
Medtronic StrataMR™ Valves and Shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to noninvasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.

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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K181622 510(k) Summary

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Date Summary Prepared	September 28, 2018

Subject Device

Trade Name	StrataMR™ Valves and Shunts (Guider Tool)
Common Name	Hydrocephalus Shunt
Classification Name	Central nervous system fluid shunt and components 21 CFR 882.5550 Class II
Product Code	JXG

Predicate Device K152700

Trade Name	Medtronic StrataMR™ Valves and Shunts
Common Name	Hydrocephalus Shunt
Classification Name	Central Nervous System Fluid Shunt and Components 21 CFR 882.5550 Class II
Product Code	JXG

Subject Device Description

The Medtronic StrataMR™ valves are implantable adjustable valves for the management of hydrocephalus. The valves and their associated catheters drain Cerebrospinal Fluid (CSF) from the ventricles in the brain into the peritoneal cavity or the right atrium of the heart, where it is absorbed by the body. Before and after implantation, the pressure/flow characteristics of the Medtronic StrataMR™ valve can by modified by the StrataMR adjustment tool.

The original StrataMR adjustment tools, including handheld locator, indicator, and adjustment tool, are designed to allow the user to determine the pressure/performance level setting of StrataMR valves and adjust the setting when needed. In this 510(k) submission, Medtronic is proposing to add an additional component, guider tool, to the StrataMR adjustment tools, to improve the method to reliably adjust the StrataMR valve, cleared in K152700.

Intended Use/Indications for Use

Medtronic StrataMR Valves and Shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to noninvasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.

Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device
The previously cleared StrataMR valve and shunt system, K152700, includes StrataMR valves, shunts, and StrataMR adjustment tools which are designed to read and adjust the pressure/ performance level setting of StrataMR. There is no change to these previously cleared StrataMR valves or shunts.

The difference between the proposed StrataMR adjustment tools and the currently available StrataMR adjustment tools is the following modification: the addition of a fourth component called the guider tool. This tool is intended to improve the ability of users to reliably adjust the StrataMR valve. This change does not affect the intended use of the system.

Feature	K181622 Subject Device	K152700 Predicate Device	Discussion
Indications for Use	Medtronic StrataMR™ Valves and Shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to noninvasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.	Medtronic StrataMR™ Valves and Shunts are designed to provide continuous cerebrospinal fluid (CSF) flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The design enables the physician to noninvasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.	Identical
Components	4 – locator tool, indicator tool, adjustment tool, guider tool	3 – locator tool, indicator tool, adjustment tool	Similar. The only difference between the modified device and the predicate is that an additional guider Tool is added to the system, which is intended to be used together with the locator Tool and adjustment Tool during the adjustment process, in order to reduce the risk of rotor foot being positioned on top of the wall. Risk assessment shows introduction of the guider tool does not introduce new unacceptable risk. Design verification and validation studies demonstrated that the proposed modified device meets the performance requirement.

Feature	K181622 Subject Device	K152700 Predicate Device	Discussion
Patient - contacting materials	Locator Tool: Clear Polycarbonate Indicator Tool: polycarbonate Adjustment Tool: Aluminum Guider tool: Clear Polycarbonate	Locator Tool: Clear Polycarbonate Indicator Tool: polycarbonate Adjustment Tool: Aluminum	Similar. The only difference between the modified device and the predicate is that an additional guider tool is added to the system. However, the patient contacting material from the guider tool is identical with the patient contacting material of the locator tool in formulation, processing, geometry, and no other chemicals have been added. Therefore, the modified StrataMR adjustment tool is substantially equivalent to the original device, from a biocompatibility perspective.
Packaging	Reusable, magnetically shielded case. Foam insert is updated to accommodate the guider tool	Reusable, magnetically shielded case with foam insert	Similar. The only difference is the addition of the guider tool to the package, and the foam insert update to accommodate the guider tool. Transportation study was conducted to demonstrate that the packaging can protect the device from damage, and product passed functional requirements after transportation simulation.
Operating Principal	Guider Tool provides a defined distance for the users to rotate adjustment tool in order to prevent the rotor foot from being positioned on top of wall. Indicator Tool is used with locator tool to couple with valve magnet to read the valve setting. Adjustment Tool is used to couple with valve magnet and rotate to the designed valve setting.	Indicator Tool is used with locator tool to couple with valve magnet to read the valve setting. Adjustment Tool is used to couple with valve magnet and rotate to the designed valve setting. At the end of the adjustment, indicator tool is used with locator tool to confirm the valve setting.	The operation principle to adjust the valve setting is similar. The operation principle for the StrataMR valve setting reading and adjustment is equivalent between the predicate and proposed device. The difference is the supplementary steps after the pressure level setting steps, which includes turning the adjustment tool (which is attached to the guider tool) clockwise

Feature	K181622 Subject Device	K152700 Predicate Device	Discussion
	At the end of the adjustment, indicator tool is used with locator tool to confirm the valve setting.		and counter-clockwise at a certain distance above the valve to remove the rotor foot from the MRI resistance wall, if the rotor foot was left on top of the wall from the previous adjusting steps. The distance above the valve is controlled by the guider tool. This supplementary step does not change the fundamental operation principle. Design verification and validation studies demonstrated that the modified StrataMR adjustment tools meet the functional requirement of adjusting the pressure level of StrataMR valves.
Cleaning & Sterilization	Non-sterile and reusable. Tools can be cleaned with warm water and mild detergent (5% Dawn soap/95% DI water) before use.	Non-sterile and reusable. Tools can be cleaned with warm water and mild detergent (5% Dawn soap/95% DI water) before use.	Similar. The only difference is the addition of the guider Tool. Design verification study was conducted to demonstrate that the guider Tool can withstand the cleaning with warm water and mild detergent, without exhibiting cracking or removal of marking.

Summary of Design Performance Testing

Non-Clinical

Results of verification and validation testing met pre-established acceptance criteria: 1) that when the rotor foot was placed on top of an MRI resistance wall, use of the guider tool can remove the rotor foot from the wall and position it to a pressure-level-setting well after the adjustment procedure and 2) use of guider tool will not inadvertently change the pressure level setting. This was done by varying the configuration to represent a worst-case scenario involving misalignment and off-centering, which demonstrates that the modified StrataMR adjustment tool met the performance specification.

In order to reach 95% confidence and 90% reliability interval, 29 guider tools were used together with locator tool and adjustment tool to conduct the test on 29 StrataMR valves.

Design verification and validation studies demonstrated that the modified StrataMR adjustment tool meet the functional requirement of adjusting the pressure level setting of StrataMR: use of the guider tool did not inadvertently change the setting.

Human Factors

The design validation study is intended to validate that under simulated use conditions, users can adjust the setting of the StrataMR valve with the new guider tool together with the existing adjustment tools, and the rotor foot does not reside on an MRI resistance wall at the end of the adjustment procedure.

Testing was conducted in an environment similar to an office setting where post-operative adjustment may occur. The evaluators for this validation study were neurosurgical personnel (attending neurosurgeons, residents, physician assistants, or clinical staff) with experience managing StrataMR or Strata-type valves. Two plastic anatomical model heads with imitation skin were used to simulate the clinical use, with the valve positioned under the imitation skin so that it was not visible to the evaluator. 14 clinician users were selected as evaluators and each evaluator was requested to perform 6 adjustments, and the total number of adjustment cycles was 84.

Biocompatibility

No new biocompatibility testing was conducted on the new Guider Tool because it was fabricated from similar materials as the predicate StrataMR Adjustment Tools. Therefore, the following biocompatibility testing was leveraged from the predicate device (K152700).

- ISO 10993-5 Third edition 2009-06-01
  Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01
  Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 Second edition 2006-08-15
  Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Conclusion

The performance testing demonstrates that the device is safe, as effective, and performs as well as or better than the predicate. The proposed modification of the StrataMR adjustment tools does not affect the intended use of the device. Therefore, it is concluded that the proposed modification of the StrataMR adjustment tool is substantially equivalent to the original StrataMR adjustment tool.