DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2016

Medtronic Neurosurgery
Mr. Deep Pal
Manager, Regulatory Affairs
125 Cremona Drive
Goleta, California 93117

Re: K152700
Trade/Device Name: Medtronic StrataMR™ Valves and Shunts
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: March 4, 2016
Received: March 7, 2016

Dear Mr. Deep Pal:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152700

Device Name
Medtronic StrataMR™ Valves and Shunts

Indications for Use *(Describe)*
The 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 non-invasively 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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510(k) Summary – K152700

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner: Medtronic Neurosurgery
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Date Summary Prepared: March 25, 2016

Trade or Proprietary Name: Medtronic StrataMR™ Valves and Shunts

Common Name: Hydrocephalus Shunt

Classification Name: Shunt, Central Nervous System and Components
(21 CFR §882.5550, Product Code JXG)

Predicate Device: Medtronic PS Medical Strata Type Valve (K060681)

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. The Medtronic StrataMR™ valve incorporates a ball and cone pressure valve in series with a normally closed siphon control mechanism. Flow control is achieved and retrograde flow is prevented by combined resistance of the ball and cone and siphon control diaphragm. Before and after implantation, the pressure/flow characteristics of the Medtronic StrataMR™ valve can by modified by means of a magnetic adjustment tool.

Indications for Use:

The 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 non-invasively adjust valve pressure/performance level pre- and post-implantation by using magnetic adjustment tools without the need for radiographic confirmation.

Summary of Technological Characteristics Compared to the Predicate Device:

The StrataMR™ valve incorporates the same basic technological characteristics as the predicate device, which include: (1) adjustable magnetic valve mechanism with five discrete pressure level settings, (2) occluders for selective flushing, (3) plastic needle guard base, (4) central reservoir, which may be injected with a 25-gauge or smaller non-coring needle, (5) radiopaque tantalum-impregnated direction arrow for showing flow direction, (6) indicators for valve performance level identification (discernible by x-ray), and (7) integrated siphon control mechanism (Delta Chamber). Both StrataMR™ and the predicate device are fabricated with a molded polypropylene base invested in a silicone elastomer housing with a concave bottom.

Changes to the device design relative to the predicate did not affect the fundamental technology, but were made to improve resistance to adjustment during MR exposure. These changes include:

- Modifications to the geometries and specific material formulations of internal valve mechanism components
- Modifications to the ergonomics of the adjustment tools and incorporation of a stronger adjustment tool magnet to accommodate the changes to the valve mechanism

Bench Testing:

The following bench testing was submitted in support of substantial equivalence.

Test	Test Method Summary	Results
Resistance to leakage	Resistance to leakage was measured using air. The valves were required to show no leakage for 5 minutes with a differential pressure from inside to outside of 1 m H_2O.	All valves met acceptance criteria, demonstrating that there are no concerns regarding valve integrity/ leakage relative to the predicate device.
Reservoir dome needle puncture	Reservoir domes were required to show no leakage when repeatedly punctured with a non-coring needle under pressure.	
Dynamic breaking strength	Tension was applied in the flow direction, leading to an elongation of the shunt of 10% or a maximum force of 5 N. Shunts were required to exhibit no break, rupture or disconnection after 100,000 cycles 1.0 ± 0.2 Hz.	

Test	Test Method Summary	Results
Pressure/flow	Pressure/flow performance was tested according to ISO 7197:2006. The measured pressure has to remain inside the manufacturer's specifications.	All valves met acceptance criteria, demonstrating that there are no concerns regarding pressure/flow performance relative to the predicate device.
Siphon control device casing effect	This test compared valve pressure at -50 cm hydrostatic pressure with valve pressure at 0 cm hydrostatic pressure. The difference was required to meet manufacturer's specifications.	
Ability to withstand overpressure	After application of positive pressure of 1 m water to the open shunt per ISO 7197:2006, valves were required to meet pre-established pressure/flow specifications.	
Bursting pressure	After application of positive pressure of 2 m water per ISO 7197:2006, valves were required to meet pre-established pressure/flow specifications.	
Long term stability	Valves were placed in a water bath with a temperature of 37°C ± 5 while pumping water through the valves at an average flow rate of 20 mL/h for 28 days. During this time, valves were required to maintain pre-established pressure/flow specifications.	
Identification of shunts *in vivo*	Valves underwent X-ray imaging. The valve identification markers must be visible and the valve setting must be readable in the X-ray images.	All valves met acceptance criteria, demonstrating that there are no concerns regarding identification of the valve via X-ray relative to the predicate device.
Post-MRI functional testing	Valves were exposed to multiple MRI exposures in clinically relevant orientation. After MRI exposure, valves were required to: (1) maintain the pre-conditioning pressure setting, (2) be able to be read and adjusted, and (3) meet pre-established pressure/flow specifications.	All valves met acceptance criteria, demonstrating that there are no concerns regarding valve performance after MRI exposure relative to the predicate device.

Test	Test Method Summary	Results
Design validation testing	Surgeon evaluators read and adjusted valves, both prior to and after implantation in cadavers.	In all cases evaluators were able to successfully read and adjust the valves, demonstrating that there are no concerns related to valve readability/ adjustability relative to the predicate device.
MRI safety testing	- Magnetically induced displacement force testing per ASTM F2052-15 - Magnetically induced torque testing per ASTM F2213-06 - Radio frequency induced heating testing per ASTM F2182-11a - Image artifact testing per ASTM F2119-07	Test results demonstrated that StrataMR valves are MR conditional and that there are not MRI safety concerns relative to the predicate device when scanned according to the MR conditions specified in the labeling.

In all cases, the results of bench testing met applicable pre-established acceptance criteria and raised no concerns regarding safety and effectiveness relative to the predicate device. Therefore, the bench testing summarized above supports the substantial equivalence of StrataMR™ and the predicate device.

Biocompatibility Testing:
The following biocompatibility testing was submitted in support of substantial equivalence.

StrataMR Shunt		
Test	**Test Method Summary**	**Results**
Cytotoxicity	*Test method: per ISO 10993-5:2009* ISO MEM Elution using L929 cells in triplicate. Extracted at 37°C for 24 hr in MEM and incubated at 37°C for 48 hr). Examined microscopically for abnormal cell morphology and cellular degeneration.	**Pass** Extract showed no evidence of causing cell lysis or toxicity (score = 0). Test article met requirements of the test (score ≤ 2).
Irritation	*Test method: per ISO 10993-10:2010* ISO Intracutaneous Study in Rabbits. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Observations for erythema and edema conducted at 24, 48, and 72 hr after injection.	**Pass** Scores = 0.0 for saline and 0.1 for oil. Extracts met requirements of the test (score of 1.0 or less).

StrataMR Shunt		
Test	**Test Method Summary**	**Results**
Acute systemic toxicity	*Test method: per ISO 10993-11:2006* ISO Systemic Toxicity Study in Mice. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Observations for signs of systemic toxicity conducted at times 0, 4, 24, 48, and 72 hrs after injection.	**Pass** No mortality or evidence of systemic toxicity from extracts. Extracts met requirements of the test.
Material-mediated pyrogenicity study	*Test method: per ISO 10993-11:2006 & USP <151>* USP Material-Mediated Pyrogen Study. Extracted in sterile, nonpyrogenic sodium chloride (saline) at 70°C for 24 hr. Rectal temperatures measured prior to injection and at 30 min intervals between 1 and 3 hours after injection.	**Pass** Total temperature rise during 3 hr period was 0.5°C (max rise of 0.2°, 0.2°, and 0.1°C for three rabbits). Test article judged nonpyrogenic. Total temp rise within acceptable USP limits (no single animal showed rise of ≥0.5°C and total temp rise was not >3.3°C).
Sensitization	*Test method: per ISO 10993-10:2010* ISO Guinea Pig Maximization Test. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Sites were scored for dermal reactions at 24 and 48 hr after challenge patch removal.	**Pass** Test article not a sensitizer (grade = 0 for saline and oil). Extracts showed no evidence of causing delayed dermal contact sensitization.
Genotoxicity	*Test method: per ISO 10993-3:2003* Bacterial Reverse Mutation Study (AMES) using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and *Escherichia coli* strain WP2*uvrA,* with and without metabolic activation. Extracted separately in 95% ethanol and saline at 70°C for 24 hr. Mean number of revertants for test plates compared to mean number for negative controls after 2 days incubation at 37°C.	**Pass** Both extracts nonmutagenic to all test strains (no case of ≥ 2-fold increase in mean number of revertants for TA98, TA100, and WP2*uvrA*; no case of ≥ 3-fold increase for TA1535 and TA1537).
	Test method: per ISO 10993-3:2003 Mouse Lymphoma Assay using L5178Y/TK$^{+/-}$ cell line, heterozygous at thymidine (TK) locus, with and without metabolic activation. Extracted separately in RPMI$_0$ culture medium (37°C for 72 hr) and 95% ethanol (70°C for 24 hr).	**Pass** Both extracts not mutagenic. Extracts did not cause a ≥ 2-fold increase in mean mutant frequency.
	Test method: per ISO 10993-3:2003 Mouse Peripheral Blood Micronucleus Study to	**Pass** Test article did not induce

StrataMR Shunt		
Test	**Test Method Summary**	**Results**
	determine cytogenetic damage resulting in micronuclei in mouse peripheral blood. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Mice injected intraperitoneally for 3 days and observed for general health. Blood collected on day 4 to evaluate reticulocytes for micronuclei.	micronuclei in mice. No significant increase in % micronucleated reticulocytes for both extracts. No biologically relevant changes in % reticulocytes.
Subchronic/subacute toxicity	*Test method: per ISO 10993-11:2006* ISO Four Week Toxicity Study in Rat, Repeated Parenteral Administration of Two Extracts. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Daily IV injections of saline extract and intraperitoneal injections of oil extract on days 1, 4, 8, 12, 15, 19, 22, and 26. Observed daily for general health and weekly for detailed health exams. Body weight measured at days 0, 8, 15, 22, 28, and 29. Blood samples taken on day 29 for hematology and clinical chemistry.	**Pass** Extract did not produce systemic toxicity in rats. Clinical observations, body weights, hematology, clinical chemistry, necropsy results, organ weights, organ/body weight ratios, and organ/brain weight ratios were similar between test and control groups. No microscopic changes due to test article.
Implantation	*Test method: per ISO 10993-6:2007* ISO Subcutaneous Implantation Study in Rabbits, 13 Weeks. StrataMR with catheter injected subcutaneously for 13 weeks. Implant sites examined macroscopically and microscopically to define any tissue response.	**Pass** Macroscopic reaction not significant compared to negative control article. Microscopic evaluation score = 2.3 compared to control. Test article classified as nonirritant compared to negative control (score = 0.0-2.9)

StrataMR Adjustment Tools Components		
Test	**Test Method Summary**	**Results**
Cytotoxicity	Test articles: adjustor, locator, and indicator housings *Test method: per ISO 10993-5:2009* ISO MEM Elution using L929 cells in triplicate. Extracted at 37°C for 24 hr in MEM and incubated at 37°C for 48 hr). Examined microscopically for abnormal cell morphology and cellular degeneration.	**Pass** Extracts showed no evidence of causing cell lysis or toxicity (scores = 0). Test articles met requirements of the test (score ≤ 2).

StrataMR Adjustment Tools Components		
Test	**Test Method Summary**	**Results**
Irritation	Test article: adjustor housing *Test method: per ISO 10993-10:2010* ISO Intracutaneous Study in Rabbits. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Observations for erythema and edema conducted at 24, 48, and 72 hr after injection.	**Pass** Scores = 0.0 for saline and 0.2 for oil. Extracts met requirements of the test (score of 1.0 or less).
Acute systemic toxicity	Test article: adjustor housing *Test method: per ISO 10993-11:2006* Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Observations for signs of systemic toxicity conducted at times 0, 4, 24, 48, and 72 hrs after injection.	No mortality or evidence of systemic toxicity from extracts. Extracts met requirements of the test.
Sensitization	Test article: adjustor housing *Test method: per ISO 10993-10:2010* ISO Guinea Pig Maximization Test. Extracted separately in sodium chloride (saline) and sesame oil at 70°C for 24 hr. Sites were scored for dermal reactions at 24 and 48 hr after challenge patch removal.	**Pass** Test article not a sensitizer (grade = 0 for saline and oil). Extracts showed no evidence of causing delayed dermal contact sensitization.

In all cases, StrataMR™ valves and adjustment tools passed biocompatibility testing, demonstrating that the StrataMR™ design does not raise any biocompatibility concerns relative to the predicate device. Therefore, the biocompatibility testing summarized above supports the substantial equivalence of StrataMR™ to the predicate device.

Conclusion:

Based on the indications for use, design and technology similarities, and performance testing performed on the proposed device, it can be concluded that the Medtronic StrataMR™ valves and shunts are substantially equivalent to the Strata II Valves cleared under K060681.