August 24, 2018

Medtronic Neurovascular
Amnon Talmor
Principal Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K181060
Trade/Device Name: Solitaire 2™ and Solitaire™ Platinum Revascularization Devices
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
Regulatory Class: Class II
Product Code: POL, NRY
Dated: May 31, 2018
Received: June 1, 2018

Dear Amnon Talmor:

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)*
K181060

Device Name
Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices

Indications for Use *(Describe)*

1. The Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

2. The Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

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.

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510(K) Summary - K181060

510(k) Owner:	Medtronic Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Amnon Talmor Principal Specialist, Regulatory Affairs Telephone: (949) 297-9270 E-mail: amnon.talmor@medtronic.com

Date Summary Prepared:	August 10, 2018
Trade Name of Device:	Solitaire™ 2 and Solitaire™ Platinum Revascularization Devices
Common Name of Device:	Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment; Catheter, thrombus retriever
Classification of Device:	21 CFR 882.5600 and 21 CFR 870.1250, Class II
Product Code:	POL, NRY
Primary Predicate Devices:	Solitaire™ 2 Revascularization Device K162539
Additional PredicateDevices:	Solitaire™ Platinum Devices (K153071, K160641 and K161879)

Device Description:

The Solitaire™ 2 and Solitaire™ Platinum Revascularization Devices is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion in the neurovasculature such as the internal carotid artery (ICA), M1 and M2 segments of the middle cerebral artery, basilar and the vertebral arteries. The distal nitinol portion of the subject device facilitates clot retrieval and has Platinum/Iridium radiopaque markers on the proximal and distal ends and, for some SKUs, at several locations along the body of the stent. The devices are supplied sterile and are intended for single-use only.

The purpose of this submission is a labeling change to include an alternative aspiration source in addition to the 60 cc syringe when using the Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices.

The indications for use for the subject device are as follows:

1. The Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.
2. The Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

Device Comparison:

Table 1 below provides a comparison between the subject, the primary predicate and additional predicate devices. All aspects of the design—including stent sizes, marker spacing, device and packaging materials, sterilization methods and how supplied—remain the same.

Table 1: Comparison between the proposed Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with the alternative aspiration source to the primary predicate and additional predicate Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices						
	Primary Predicate: Solitaire™ 2 Revascularization Device with syringe aspiration (K162539)	**Additional Predicate devices (Solitaire™ Platinum Revascularization Device)**			**Subject: Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with Riptide™ Aspiration System**	**Rationale for Difference (if applicable)**
		K153071	**K161879**	**K160641**		
Product code	POL and NRY	NRY			Same as primary predicate (K162539)	N/A
Indication for Use	The Solitaire™ 2 Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset. The Solitaire™ Revascularization Device is indicated to restore	The Solitaire™ Platinum Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.			Same as primary predicate (K162539)	N/A

Table 1: Comparison between the proposed Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with the alternative aspiration source to the primary predicate and additional predicate Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices						
	Primary Predicate: Solitaire™ 2 Revascularization Device with syringe aspiration (K162539)	**Additional Predicate devices (Solitaire™ Platinum Revascularization Device)**			**Subject: Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with Riptide™ Aspiration System**	**Rationale for Difference (if applicable)**
		K153071	**K161879**	**K160641**		
	blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.					
Principle of operation	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke The device is used in the neurovasculature to restore blood flow by removing thrombus	The device is used in the neurovasculature to restore blood flow by removing thrombus			Same as primary predicate (K162539)	N/A
Procedural steps aspiration source	Syringe				Aspiration Device	Bench testing and a review of relevant clinical literature demonstrates the alternative aspiration source does not raise any

Table 1: Comparison between the proposed Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with the alternative aspiration source to the primary predicate and additional predicate Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices						
	Primary Predicate: Solitaire™ 2 Revascularization Device with syringe aspiration (K162539)	**Additional Predicate devices (Solitaire™ Platinum Revascularization Device)**			**Subject: Solitaire™ 2 and Solitaire ™ Platinum Revascularization Devices used with Riptide™ Aspiration System**	**Rationale for Difference (if applicable)**
		K153071	**K161879**	**K160641**		
						new issues of safety or effectiveness.
Device sizes (mm)	4x15 4x20 4x40 6x20 6x30	4x20 4x40 6x20	4x20x05 6x24x06	6x40x10	4x15 4x20 4x40 6x20 6x30 4x20x05 6x24x06 6x40x10	The subject device scope includes the primary predicate and additional predicate devices. The sizes used in the simulated clot retrieval testing were identical to the primary predicate device and representative of the additional predicate devices.
How supplied	Stored within dispenser coil, Tyvek pouch and shipping carton					N/A
Sterilization method	Ethylene oxide					N/A
Device materials						
Stent	Nitinol					N/A
Push wire	Nitinol					
Radiopaque markers	90% Platinum/10% Iridium					
Push-wire shrink Tubing	PTFE					

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		K153071	**K161879**	**K160641**		
Introducer Sheath	PTFE/Grilamid					
Shrink tubing	PTFE					

Performance Data

Medtronic Neurovascular performed the following non-clinical bench tests to support the use of the alternative aspiration source with the Solitaire™ 2 and Solitaire™ Platinum Revascularization Devices:

Test	**Test Method Summary**	**Conclusions**
Vacuum pressure testing	Purpose: Compare the ability of the alternative aspiration device to deliver vacuum pressure to the distal tip of the catheter to a 60 cc syringe. Method: The vacuum pressure was measured at the distal tip of the aspiration catheter when generated from the alternative aspiration device at various vacuum pressure settings, as well as from a 60 cc VacLok® Syringe.	Vacuum pressure delivered to the distal tip of the catheter from a 60 cc syringe exceeded the pressure delivered from the alternative aspiration device.
Simulated clot retrieval testing	Purpose: Compare the clot retrieval performance of the subject device when used with the alternative aspiration source to the cleared device use with a 60 cc syringe.	Clot retrieval performance of the subject device was equivalent to the predicate performance.

In addition to the above tests, Medtronic Neurovascular conducted a comprehensive review of relevant clinical literature to assess whether any issues of safety or effectiveness were raised by the clinical use of the alternative aspiration source with the Solitaire™ 2 and Solitaire™ Platinum Revascularization Devices.

Conclusion

Non-clinical bench testing and a review of relevant literature demonstrate the subject device is substantially equivalent to the predicate Solitaire™ 2 and Solitaire™ Platinum Revascularization Devices and does not raise any new questions of safety and effectiveness.