DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2017

Medtronic Vascular, Inc.
Mr. Aaron Hage
Regulatory Affairs Specialist
3033 Campus Drive, N550
Plymouth, MN 55441

Re: K170191
Trade/Device Name: SilverHawk Peripheral Plaque Excision System,
TurboHawk Peripheral Plaque Excision System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: May 18, 2017
Received: May 19, 2017

Dear Mr. Hage:

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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K170191

Device Name
SilverHawk Peripheral Plaque Excision System
TurboHawk Peripheral Plaque Excision System

Indications for Use *(Describe)*
The SilverHawk and TurboHawk Peripheral Plaque Excision System are intended for use in atherectomy of the peripheral vasculature. The SilverHawk and TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

The TurboHawk Catheter (THS-LS-C, THS-LX-C) is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified 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.

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510(k) Summary

SilverHawk™ Peripheral Plaque Excision System
TurboHawk™ Peripheral Plaque Excision System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1 Submitter Information

Applicant	Medtronic Vascular, Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Aaron Hage Regulatory Affairs Specialist
Date Prepared	June 16, 2017

2 Subject Device

Device Trade Name	SilverHawk™ Peripheral Plaque Excision System TurboHawk™ Peripheral Plaque Excision System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular

3 Predicate Devices

Device Trade Name	SilverHawk™ Peripheral Plaque Excision System
510(k) Numbers	K061063; K061188
510(k) Clearance Dates	May 18, 2006; October 23, 2006
Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
510(k) Numbers	K103618; K111723
510(k) Clearance Dates	January 5, 2011; October 27, 2011

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SilverHawk ™ and TurboHawk™ Peripheral Plaque Excision System 510(k) Summary

4 Reference Device

Device Trade Name	HawkOne™ Directional Atherectomy System
510(k) Numbers	K161361; K141801
510(k) Clearance Dates	October 14, 2016; October 16, 2014

5 Device Description

The SilverHawk and TurboHawk Peripheral Plaque Excision System consists of a Catheter and Cutter Driver, which are packaged separately, but shipped and used together during the plaque excision procedure. The catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the Catheter contains a connector and positioning lever designed to fit into a small, disposable, battery driven Cutter Driver, which powers the device.

The SilverHawk and TurboHawk Peripheral Plaque Excision System each have two switches: 1) the Cutter Driver main power switch and 2) the Catheter thumb switch. The Cutter Driver main power switch supplies power to the device when turned ON. When the thumb switch is fully forward (OFF), the cutting blade is closed and stored in the cutter housing with the motor off. This position is used during delivery of the device to the target lesion. Once the device has been positioned the Catheter thumb switch is pulled proximally to the ON position to activate the drive shaft and engage the cutter. Pulling back on the Catheter thumb switch simultaneously turns on the motor and causes the distal portion of the cutter housing to deflect, forcing the device against the target lesion. At the same time, this motion exposes the inner rotating blade, preparing the device for lesion treatment. With the blade spinning, the Catheter is slowly advanced across the lesion, "shaving" occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the Catheter thumb switch distally, deactivating the drive shaft, disengaging the cutter, and aligning the cutter and housing. The Catheter thumb switch is fully advanced distally to the OFF position in order to move the cutter forward within the tip and pack the excised plaque into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

The SilverHawk and TurboHawk Peripheral Plaque Excision System uses the following materials: stainless steel, platinum/iridium, carbide w/ 12% nickel binder, titanium, delrin, polyimide, PET lined tecothane, pebax, nylon, Teflon, tungsten carbide, ABS, PVC, silicone, Santoprene, polycarbonate, polypropylene and hydrophilic coating.

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SilverHawk ™ and TurboHawk™ Peripheral Plaque Excision System 510(k) Summary

6 Intended Use

The Intended Use of the proposed devices are the same as the predicate devices:

The SilverHawk and TurboHawk Peripheral Plaque Excision System are intended for treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries.

7 Indications for Use

The Indication for Use statement of the proposed devices are the same as the predicate devices:

The SilverHawk and TurboHawk Peripheral Plaque Excision System are intended for use in atherectomy of the peripheral vasculature. The SilverHawk and TurboHawk Catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.

The TurboHawk Catheter (THS-LS-C, THS-LX-C) is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions.

The proposed change impacts the indications for use by removing contraindications that do not meet the FDA definition of a contraindication from the predicate devices. The removal of these contraindications does not change the intended use of the device. Additionally, removal of these contraindications would not significantly affect the safety and effectiveness of the device as these contraindications have not been demonstrated to present risks that clearly outweigh any possible benefits.

8 Comparison of Technological Characteristics

The proposed SilverHawk and TurboHawk Peripheral Plaque Excision System is substantially equivalent to the legally marketed SilverHawk and TurboHawk devices cleared by FDA under premarket notification: K111723, cleared October 27, 2011; K103618, cleared January 5, 2011; K061188, cleared October 23, 2006; K061063, cleared May 18, 2006.

The proposed and predicate devices share the following technological characteristics:

- Intended Use
- Fundamental scientific technology
- Principles of Operation
- Conditions of Use
- Sterilization method, parameters, and sterility assurance level

Additionally, labeling, device design, device materials, packaging material, manufacturing process, manufacturing and sterilization site, of the proposed devices are similar to the legally marketed devices and would not significantly affect the safety or effectiveness of the devices.

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SilverHawk ™ and TurboHawk™ Peripheral Plaque Excision System 510(k) Summary

Since the clearance of the predicate device, device component changes have been made to specific models of the SilverHawk and Turbo Hawk devices such as, increase in the number of tip vent holes (MEC Technology), softer durometer Tecothane, smaller flush lumen, increased tip length, new torque and drive shafts, and updated cutter breaker design. Please refer to Section 9 for details and related testing for all device changes.

9 Performance Testing Summary

To demonstrate substantial equivalence of the proposed SilverHawk and TurboHawk Peripheral Plaque Excision System to the predicate devices, the following bench testing was performed:

Proposed Model	Changes Assessed	Test Method Use to Evaluate Change
SilverHawk LS-M, MS-M, LX-M	• MEC Technology: Increased number of tip vent holes	• Device Inspections • Cutter Height • Cycle and Life • Carbide Edge Attachment • Repeated Cutter Spin Down and Packing • Coating Integrity • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Test
SilverHawk SXL	• Tip Length increased • Addition of vent holes • Addition of a distal plunger reinforcement • Softer Durometer Tecothane • Smaller Flush Lumen	• Device Inspections • Cutter Height • Cycle and Life • Carbide Edge Attachment • Repeated Cutter Spin Down and Packing • Coating Integrity • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Test • Flush Test • Tissue Removal Cycle Test
SilverHawk EXL	• Tip length increased and torque shaft length reduced • MEC Technology: Increased number of tip vent holes • Softer durometer Tecothane • Increase shaft adaptor inner diameter	• Device Inspections • Cutter Height • Cycle and Life • Carbide Edge Attachment • Repeated Cutter Spin Down and Packing • Coating Integrity • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Test • Flush Test

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SilverHawk ™ and TurboHawk™ Peripheral Plaque Excision System 510(k) Summary

Proposed Model	Changes Assessed	Test Method Use to Evaluate Change
		• Tissue Removal Cycle Test
SilverHawk SS+, ES+	• Modified asymmetrical housing with directional feature (SS+ crossing profile increased) • Cutter mouth opening extended • MEC Technology: Increased number of tip vent holes • Addition of a torque transmission feature (ES+ only) • Drive shaft coil winding • New torque shaft • Tip-assembly (SS+ only)	• Device Inspections • Cutter Height • Cycle and Life • Carbide Edge Attachment • Repeated Cutter Spin Down and Packing • Coating Integrity • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Test • Flush Test • Tissue Removal Cycle Test
TurboHawk LS-M, LX-M	• New drive shaft • Improved “Urge” shape on the distal end of the torque shaft • MEC Technology: Increased number of tip vent holes	• Device Inspections • Cutter Height • Cycle and Life • Carbide Edge Attachment • Repeated Cutter Spin Down and Packing • Coating Integrity • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Tests • Flush Test • Tissue Removal Test • Tissue Flushing Tool Deployment
TurboHawk LS-C, LX-C	• Updated cutter breaker design to mimic the High Efficiency Cutter design used on the small vessel TurboHawk device (K103618, cleared on January 5, 2011). • Reduced diameter of the distal tip	• Device Inspections • Cycle and Life • Repeated Cutter Spin Down and Packing • Simulated Use (trackability, rotational fatigue, cycling and cutting) • Shaft Torque Test • Device Tensile Tests • Tissue Distal Flushing Tool (DFT) Deployment
TurboHawk SX-C, SS-C, SS-CL	• Change of slider cover component, addition of a compression force specification • Replacement of shaft adaptor washer with the shaft adaptor washer used to build the TurboHawk predicate	• Device Inspections • Driveshaft Compression

The results from these tests demonstrate that the technological and performance characteristics of the proposed SilverHawk and TurboHawk devices perform in a manner equivalent to the predicate devices currently on the market.

10 Conclusions

Based on the intended use, indications for use, technological characteristics, performance Medtronic considers the proposed SilverHawk and TurboHawk Peripheral Plaque Excision Systems to be substantially equivalent to the currently marketed SilverHawk and TurboHawk Peripheral Plaque Excision System (K111723, K103618, K061188, K061063).