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

October 14, 2016

Medtronic Vascular, Inc.
Ms. Rupali Gupta
Senior Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K161361
Trade/Device Name: HawkOne Directional Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: August 31, 2016
Received: September 1, 2016

Dear Ms. Gupta:

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,

Brian D. Pullin -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)*
K161361

Device Name
HawkOne Directional Atherectomy System

Indications for Use *(Describe)*
The HawkOne Directional Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

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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Medtronic

510(k) Summary

HawkOne™ Directional Atherectomy 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. 4600 Nathan Lane N Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Rupali Gupta Senior Regulatory Affairs Specialist
Date Prepared	May 13, 2016

2. Subject Device

Device Trade Name	HawkOne Directional Atherectomy System
Device Common Name	Catheter, Peripheral, Atherectomy
Classification Name	Intraluminal Artery Stripper 21 CFR 870.4875, Product Code MCW
Classification Panel	Cardiovascular

3. Predicate Device

Device Trade Name	HawkOne Directional Atherectomy System (H1-LX and H1-LS)
510(k) Number	K141801
510(k) Clearance Date	October 16, 2014

4. Reference Device

Device Trade Name	TurboHawk™ Peripheral Plaque Excision System
510(k) Number	K103618
510(k) Clearance Date	January 5, 2011

5. Device Description

The HawkOne™ directional atherectomy system (HawkOne catheter and cutter driver) is designed for the treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries. When treating complex, hard, calcified lesions, pairing the HawkOne catheter with the SpiderFX™ embolic protection device mitigates risk of

distal embolization that can be generated when heavily calcified plaque breaks down. For information about the SpiderFX embolic protection device, reference the Instructions for Use provided with the device

The HawkOne catheter consists of a flexible shaft designed to track with a 0.36 mm (0.014 in) guidewire. At the distal end of the HawkOne catheter there is a small cutting unit comprised of an inner blade that rotates within a tubular housing. The proximal end of the HawkOne catheter contains a connector and cutter positioning lever (thumb switch) designed to fit into the cutter driver. The cutter driver (catalog number H1-14550) is a battery driven, internally powered device, designed to power the HawkOne directional atherectomy catheter.

The HawkOne directional atherectomy system has two switches: 1) the main power switch on the cutter driver and 2) the cutter positioning lever (thumb switch) on the HawkOne catheter. The main power switch on the cutter driver supplies power to the device when turned On. When the thumb switch is pulled proximally to the On position, the HawkOne catheter activates the drive shaft and the cutter. With the cutter engaged, the HawkOne 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 HawkOne catheter thumb switch distally, deactivating the drive shaft and disengaging the cutter. When the HawkOne catheter thumb switch is fully advanced distally to the Off position, excised tissue is packed into the tip. This cutting sequence is repeated as necessary to achieve the desired degree of plaque excision.

6. Indications for Use

The HawkOne Directional Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX Embolic Protection Device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

7. Comparison of Technological Characteristics

The primary purpose of this traditional 510(k) is to reduce the crossing profile from 2.6mm to 2.2mm by using a smaller driveshaft, cutter, and tip, compared to the HawkOne 7F device, so that the proposed HawkOne 6F device can be tracked through a 6F introducer sheath. There is also a change in the material/material supplier in this submission. When compared to the TurboHawk reference device, the proposed HawkOne 6F has an increased device RPM, improved torque shaft laminates, and includes a pre-loaded distal flush tool."

The proposed HawkOne 6F catheter will only function with the HawkOne cutter driver (H1-14550) which is currently used for the primary predicate HawkOne 7F catheters. HawkOne 6F catheters will not function and are functionally unable to connect with the previously released cutter driver (FG-02550) which is used with the reference TurboHawk catheters.

The proposed HawkOne 6F is considered to be substantially equivalent to the legally marketed HawkOne Directional Atherectomy System (referred to as HawkOne 7F), cleared by FDA under premarket notification K141801 on October 16, 2014 and TurboHawk Peripheral Plaque Excision

Medtronic

HawkOne Directional Atherectomy System 510(k) Summary

System, SX-C, SS-C, SS-CL (referred to as TurboHawk) for small vessel, cleared by FDA under premarket notification K103618 on January 05, 2011.

The proposed and predicate devices share the following technological characteristics:

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

Additionally, the indications for use, labeling, device materials, and manufacturing site and methods are similar between the proposed and marketed devices.

8. Performance Testing Summary

To demonstrate substantial equivalence of the proposed HawkOne Directional Atherectomy System (HawkOne 6F) to the predicate devices, bench testing was performed.

Using internal Risk Analysis procedures, the following tests were performed:

- Device Inspections
- Cutter Height
- Tracking Force
- Cycle and Life
- Repeated Cutter Spin Down and Packing
- Carbide Edge Attachment
- Shaft Torque Test
- DFT Torque and Pressure Test
- Device Tensile Tests
- Coating integrity
- Cut depth
- Mass Per Pass (Tissue Removal Rate)
- Embolization
- Simulated Use (trackability, rotational fatigue, cycling and cutting)
- Biocompatibility

The results from these tests demonstrate that the technological characteristics and performance criteria of the proposed HawkOne 6F devices are comparable to the predicate and reference devices and that the proposed HawkOne 6F device performs in a manner equivalent to the predicate devices currently on the market.

9. Conclusions

Based on the identical intended use, similar technological characteristics, and safety and performance testing included in this submission, Medtronic Vascular, Inc (formerly d.b.a. ev3 Inc./Covidien llc) considers the proposed HawkOne 6F device to be substantially equivalent to the currently marketed HawkOne 7F, K141801 (primary predicate) and TurboHawk, K103618 (reference) devices.