August 24, 2021

Medtronic, Inc
Jenny Andersen
Senior Director of Regulatory Affairs
4600 Nathan Lane North
Plymouth, Minnesota 55442

Re: K212027
Trade/Device Name: TurboHawk Plus Directional Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: June 29, 2021
Received: June 30, 2021

Dear Jenny Andersen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212027

Device Name
TurboHawk Plus Directional Atherectomy System

Indications for Use *(Describe)*
The TurboHawk Plus directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Plus catheter is indicated for use in conjunction with the SpiderFX embolic protection device in the treatment of severely calcified lesions. The TurboHawk Plus 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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510(k) Summary
TurboHawk Plus™ 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, Inc 710 Medtronic Parkway Minneapolis, MN 55432 Tel: 763-514-4000
Contact Person	Angela Huber Regulatory Affairs Manager 612-704-2418 angela.huber@medtronic.com
Date Prepared	June 24, 2021

2. Subject Device

Device Trade Name	TurboHawk Plus 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	TurboHawk™ Peripheral Plaque Excision System
510(k) Number	K170191[1]
Clearance Date	June 16, 2017

4. Reference Device

Device Trade Name	HawkOne Directional Atherectomy System	
510(k) Number	K161361	K141801
510(k) Clearance Date	October 14, 2016	October 16, 2014

[1] Medtronic considers the TurboHawk Plus Directional Atherectomy System to be substantially equivalent to the currently marketed TurboHawk Peripheral Plaque Excision Systems, K170191. Previous 510k clearances include; K111723, K103618, K093301.

5. Device Description

The TurboHawk Plus Directional Atherectomy System (TurboHawk Plus 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 TurboHawk Plus catheter with the SpiderFX embolic protection device mitigates risk of distal embolization that may be generated when heavily calcified plaque breaks down.

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

The TurboHawk Plus 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 TurboHawk Plus 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 TurboHawk Plus catheter activates the drive shaft and the cutter. With the cutter engaged, the TurboHawk Plus 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 TurboHawk Plus catheter thumb switch distally, deactivating the drive shaft and disengaging the cutter. When the TurboHawk Plus 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. Intended Use

The TurboHawk Plus is intended for treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in native peripheral arteries.

7. Indications for Use

The TurboHawk Plus directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The TurboHawk Plus catheter is indicated for use in conjunction with the SpiderFX embolic protection device in the treatment of severely calcified lesions. The TurboHawk Plus catheter is not intended for use in the coronary, carotid, iliac, or renal vasculature.

8. Comparison of Technological Characteristics

The TurboHawk Plus is comprised of HawkOne catheter (reference) combined with the TurboHawk cutter driver (predicate). The TurboHawk Plus device uses similar design and

materials as the predicate devices. Modifications have been made to the TurboHawk Plus device design, so the proposed device catheter can function with the predicate cutter driver. Additionally, modifications are made to allow for improved tracking, crossing, torqueability, radiopacity, as well as improved procedural efficiency with the pre-loaded distal flush tool when compared to the predicate.

TurboHawk Plus shares the following similarities to the predicate device and reference devices.

- Same intended use
- Similar indications for use
- Same fundamental scientific technology
- Same principle of operation
- Similar catheter and cutter driver materials
- Similar device dimensions and diameter of vessels
- Same lubricious coating
- Same sterility assurance level and method of sterilization
- Same packaging material and configuration

In addition, device materials, and manufacturing site and methods and labeling are similar between the proposed and legally marketed predicate device and reference devices.

9. Performance Testing Summary

To demonstrate substantial equivalence of the proposed TurboHawk Plus to the predicate device, the following performance tests were performed using internal Risk Analysis procedures:

- Device Inspections
- Simulated use (trackability, rotational fatigue, cycling and cutting)
- Kink resistance
- Heat generation
- Torsional Strength
- Tensile Strength
- Catheter to cutter driver interaction
- Cut Mass/Pass (Plaque Removal Efficiency)
- Capture Efficiency (Debris removal and collection)
- Cycle & Life
- Cutting embolization analysis
- Consistency of Tissue Removal
- Coating integrity
- Particulate evaluation

The results from these tests demonstrate that TurboHawk Plus meets the product performance specifications. The technological characteristics and performance criteria of the TurboHawk Plus

devices are comparable to the predicate device and the proposed TurboHawk Plus device performs in a manner equivalent to the predicate device currently on the market.

10. Biocompatibility Testing

The biocompatibility evaluation for the TurboHawk Plus was conducted in accordance with the principles of the ISO 10993:2018 Part 1, "Evaluation and Testing within a risk management process ".

The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Haemocompatibility –Hemolysis
- Haemocompatibility –Complement Activation
- Haemocompatibility –Partial Thromboplastin Time (PTT)
- Haemocompatibility – Thromboresistance
- Hemocompatibility - Platelet and Leukocyte Count

The TurboHawk Plus is considered biocompatible for its intended use under ISO 10993-1 category: externally communicating device, circulating blood contact with limited (<24 hour) exposure.

11. Conclusions

Based on the same intended use and indications for use, similar technological characteristics, and safety and performance testing included in this submission, Medtronic considers the TurboHawk Plus Directional Atherectomy System to be substantially equivalent to the currently marketed TurboHawk Peripheral Plaque Excision Systems, K170191.