June 8, 2023

Philips Medical Systems Nederland B.V.
Jeanette Becker
Regulatory Affairs Manager
Veenpluis 6
Best, 5684 PC
Netherlands

Re: K223918
Trade/Device Name: AltaTrack Equipment R1.2, AltaTrack Guidewire, AltaTrack 3D Hub
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQX
Dated: May 4, 2023
Received: May 11, 2023

Dear Jeanette Becker:

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,

Rohini Retarekar -S

for Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support, Structural & Vascular 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)*

K223918

Device Name
AltaTrack Equipment, AltaTrack Guidewire, AltaTrack 3D Hub

Indications for Use *(Describe)*

The AltaTrack Equipment is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Guidewire and, optionally, a catheter during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real-time of the connected AltaTrack Guidewire and, of an endovascular catheter, when combined with a AltaTrack 3D Hub.

The AltaTrack Guidewire is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter during navigation in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

The AltaTrack 3D Hub enables the visualization of a connected endovascular catheter, when used in combination with an AltaTrack Guidewire and the AltaTrack Equipment.

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

This 510(k) summary is prepared in accordance with 21 CFR §807.92.

510(k) Number: K223918

Date Prepared: December 22, 2022

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

Primary Contact Person:
Ms. Jeanette Becker
Regulatory Affairs Manager
Phone: +31 621823383
E-mail: jeanette.becker@philips.com

Devices: AltaTrack system, containing the following primary devices:

Trade Name:	AltaTrack Equipment R1.2
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQK

Trade Name:	AltaTrack Guidewire
Classification Name:	Catheter guide wire
Classification Regulation:	21 CFR, Part 870.1330
Device Class:	II
Product Code:	DQX

Trade Name:	AltaTrack 3D Hub
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQK

Predicate Devices: AltaTrack system (K201081), containing the following devices:

Trade Name:	AltaTrack equipment
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K201081, 17 December 2020
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQK

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Trade Name:	AltaTrack Guidewire
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K201081, 17 December 2020
Classification Name:	Catheter guide wire
Classification Regulation:	21 CFR, Part 870.1330
Device Class:	II
Product Code:	DQX

Trade Name:	AltaTrack Catheter
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K201081, 17 December 2020
Classification Name:	Diagnostic intravascular catheter
Classification Regulation:	21 CFR 870.1200
Device Class:	II
Product Code:	DQO

Device description: The AltaTrack system consists of the following primary devices:

The *AltaTrack Equipment R1.2* is a visualization device with Fiber Optic RealShape (FORS) technology. Its function is to create a 3D image in real time of an AltaTrack Guidewire and, optionally, an endovascular catheter when combined with AltaTrack 3D Hub, and overlay it on real-time or pre-recorded 2D fluoroscopy images and/or on pre-operative 3D CT images, if available.
The AltaTrack Equipment comprises software and hardware components (such as lasers, optical components, computer hardware, electrical and optical cabling), and a single-use, sterile, detachable component.

The *AltaTrack Guidewire* is a single-use, sterile, hydrophilic guidewire with FORS technology.
The primary function of the AltaTrack Guidewire is to direct an AltaTrack Catheter or other compatible catheter to a desired anatomical location. It can be visualized in 3D in real time by the AltaTrack equipment using FORS technology.

The *AltaTrack 3D Hub* is a single-use, sterile accessory to the AltaTrack Equipment R1.2. The AltaTrack 3D Hub connects to the luer connector of endovascular catheters. When the AltaTrack 3D Hub is connected to an endovascular catheter and is used in combination with an AltaTrack Guidewire, the AltaTrack Equipment R1.2 enables real time 3D visualization of the connected endovascular catheter.

Indications for Use: The *AltaTrack Equipment* is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Guidewire and, optionally, a catheter during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real-time of the connected AltaTrack Guidewire and, of an endovascular catheter, when combined with a AltaTrack 3D Hub.

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The *AltaTrack Guidewire* is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter during navigation in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

The *AltaTrack 3D Hub* enables the visualization of a connected endovascular catheter, when used in combination with an AltaTrack Guidewire and the AltaTrack Equipment.

Technological characteristics:

The basic design and functionality of the *AltaTrack Equipment R1.2* has the same technological characteristics as the AltaTrack equipment (R1.0), with the exception of the following differences:

- Modifications, such as the redesign of the connection box, due to the introduction of the AltaTrack 3D Hub and removal of compatibility with AltaTrack Catheters;
- Updates in Philips interventional X-ray system compatibility;
- Minor software updates due to workflow improvements and maintenance activities.

The differences between the AltaTrack Equipment R1.2 and the predicate device do not raise any new questions regarding safety or effectiveness.

As there have been no changes to the *AltaTrack Guidewire*, the technological characteristics remain the same.

The introduction of the *AltaTrack 3D Hub* enables the visualization of a conventional endovascular catheter by the AltaTrack Equipment R1.2 instead of the AltaTrack Catheter since the AltaTrack Catheter is no longer supported by AltaTrack Equipment R1.2.
Note that the fundamental scientific technology with regards to visualization of the applicable devices of the AltaTrack system remains the same.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the *AltaTrack Equipment R1.2* and the *AltaTrack 3D Hub*.
Note that the AltaTrack Catheter is no longer supported by AltaTrack Equipment R1.2 and that the AltaTrack Guidewire, remaining the same, did not require any non-clinical performance testing.

The aforementioned non-clinical performance testing demonstrates compliance with the following international and FDA recognized consensus standards and FDA guidance documents:

- [5-125] ISO 14971:2019 Third Edition 2019-12, Medical devices – Application of risk management to medical devices
- [5-134] ISO 15223-1:2021 Fourth Edition 2021-07, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied by the manufacturer- Part 1: General requirements
- [15-135] ISO 20417 First edition 2021-04 Corrected version 2021-12, Medical devices. Information to be supplied by the manufacturer
- [19-4] AAMI ANSI 60601-1:2005/R2012 and A1:2012, c1:2009/(r) and A2:2010/(r)2012, Medical electrical equipment edition 3.1 – Part 1: General requirements for basic safety and essential performance
- [19-8] IEC 60601-1-2 Edition 4.0, 2014-02, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances -- Requirements and tests

- [5-89] IEC 60601-1-6 Edition 3.1, 2013-10, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- [5-114] IEC 62366-1:2015 Edition 1.0, 2015-02, Medical devices – Application of usability engineering to medical devices (including corrigendum 1 (2016)
- [13-79] IEC 62304 Edition 1.1, 2015-06 Consolidated version, Medical device software – Software life cycle processes
- [2-258] ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- [2-248] ISO 10993-4 Third edition 2017-04, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- [2-245] ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- [2-275] ISO 10993-7 Second edition 2008-10-15, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
- [2-274] ANSI AAMI ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- [2-255] ISO 10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- [14-529] ANSI AAMI ISO 11135:2014, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices (including amendment 1 (2018).
- [14-550] AAMI ANSI ST67:2019, Sterilization of healthcare products – Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled “sterile”
- [14-514] ISO 11737-1 Third edition 2018-01 [Including AMD1:2021], Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products [Including Amendment 1 (2021)]
- [14-530] ISO 11607-1 Second edition 2019-02, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- [5-121] ISO 80369-1 Second edition 2018-11, Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements
- [5-133] ISO 80369-7 Second edition 2021-05, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff, Issued 06/06/2022,
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process": Guidance for Industry and Food and Drug Administration Staff, Issued 09/04/2020
- Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff, Issued 02/03/2016

Software verification testing of the functional, non-functional and user interface requirements as well as performance testing has been performed to cover system level requirements as well as risk control measures. Results demonstrated that all executed tests were passed.

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Non-clinical validation testing has been performed to cover the intended use, service, user needs, effectiveness of safety measures, instructions for use, and usability testing with representative intended users.

Therefore, the AltaTrack system containing the *AltaTrack Equipment R1.2,* the *AltaTrack Guidewire* and the *AltaTrack 3D Hub* is considered substantially equivalent to the AltaTrack system containing the predicate AltaTrack equipment (R1.0), the AltaTrack Guidewire and the AltaTrack Catheter, in terms of safety and effectiveness.

Summary of Clinical Performance Data:

Substantial equivalence of the *AltaTrack Equipment R1.2* and the *AltaTrack 3D Hub* did not require clinical study data, since substantial equivalence was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics; and
- Non-clinical performance testing.

These attributes demonstrated that the clinical performance of the modified devices is substantially equivalent to the predicate devices.

Substantial Equivalence Conclusion:

The AltaTrack system containing the *AltaTrack Equipment R1.2,* the *AltaTrack Guidewire* and the *AltaTrack 3D Hub* is considered substantially equivalent to the AltaTrack system containing the predicate AltaTrack equipment (R1.0), the AltaTrack Guidewire and the AltaTrack Catheter.