March 14, 2024

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

Re: K233853
Trade/Device Name: LumiGuide Wire; LumiGuide Equipment R2.0; LumiGuide 3D Hub
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DQX
Dated: December 5, 2023
Received: December 5, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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)*
K233853

Device Name
LumiGuide Wire;
LumiGuide Equipment R2.0;
LumiGuide 3D Hub

Indications for Use *(Describe)*
The LumiGuide Wire is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

The LumiGuide Equipment is a visualization device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected LumiGuide Wire 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 LumiGuide Wire and, of an endovascular catheter, when combined with a LumiGuide 3D Hub.

The LumiGuide 3D Hub enables the visualization of a connected endovascular catheter, when used in combination with a LumiGuide Wire and the LumiGuide 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 of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: December 5, 2023

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

Primary Contact Person:
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Devices: LumiGuide system, containing the following primary devices:

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

Trade Name:	LumiGuide Equipment R2.0
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQK

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

Predicate Devices: AltaTrack system (K223918), containing the following devices:

Trade Name:	AltaTrack Guidewire
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification Name:	Catheter guide wire
Classification Regulation:	21 CFR, Part 870.1330
Device Class:	II
Product Code:	DQK

Trade Name:	AltaTrack Equipment R1.2
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQX

Trade Name:	AltaTrack 3D Hub
Manufacturer:	Philips Medical Systems Nederland B.V.
Classification Name:	Programmable diagnostic computer
Classification Regulation:	21 CFR, Part 870.1425
Device Class:	II
Product Code:	DQK

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

The *LumiGuide Wire* is a sterile, single use, angiographic guidewire with Fiber Optic RealShape (FORS) technology that is available in two configurations: LumiGuide Navigation Wire 3D Ultra and LumiGuide Navigation Wire 3D Plus. The primary function of the LumiGuide Wire is to direct a catheter in endovascular procedures of the peripheral, aortic and aortic side branch vasculature. The LumiGuide Wire can be visualized in 3D in real time by the LumiGuide Equipment R2.0 using FORS technology.

The *LumiGuide Equipment R2.0* is a visualization device with Fiber Optic RealShape (FORS) technology. Its function is to create a real time 3D image of a LumiGuide Wire and, optionally, an endovascular catheter when combined with LumiGuide 3D Hub, and overlay this on real time or pre-recorded X-ray images and/or on a pre-operative CT volume. The LumiGuide Equipment R2.0 comprises software and hardware components (such as lasers, optical components, computer hardware, electrical and optical cabling), and a single-use, sterile, detachable component.

The *LumiGuide 3D Hub* is a sterile, single use accessory to the LumiGuide Equipment R2.0 that connects to the luer connector of endovascular catheters. When the LumiGuide Hub is connected to an endovascular catheter and is used in combination with a LumiGuide Wire, the LumiGuide Equipment R2.0 enables real time 3D visualization of the connected endovascular catheter.

Indications for Use: The *LumiGuide Wire* is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

The *LumiGuide Equipment* is a visualization device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected LumiGuide Wire 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 LumiGuide Wire and, of an endovascular catheter, when combined with a LumiGuide 3D Hub.

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

Technological characteristics:

The basic design and functionality of the *LumiGuide Wire* has the same technological characteristics as its predicate, AltaTrack Guidewire, with exception of the following differences:

- the length of the in-body section is changed from 120cm to 160cm.
- the *LumiGuide Wire* is available in two configurations, whereas the AltaTrack Guidewire was only available in one configuration. The only difference between the two configurations is that one can also optionally be displayed as overlay on a pre-procedural CT volume, same as the AltaTrack Guidewire, whereas the other cannot.

The differences between the modified device and the predicate device do not raise any new questions regarding safety or effectiveness.

As there are no significant changes to the *LumiGuide Equipment R2.0* and the *LumiGuide 3D Hub*, their technological characteristics remain the same as those of the previous AltaTrack branded versions.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the *LumiGuide Wire* (which is also valid for the *LumiGuide 3D Hub*) and the *LumiGuide Equipment R2.0* to cover risk control measures as well as system level requirements, such as dimensional, mechanical and packaging related requirements. Results demonstrated that all executed tests were passed.
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.
Note that the *LumiGuide 3D Hub* did not require any additional non-clinical performance testing other than the testing performed for the *LumiGuide Wire.*

The aforementioned non-clinical performance testing demonstrates compliance to the applicable international and FDA recognized consensus standards and FDA guidance documents.

Therefore, the LumiGuide system containing the *LumiGuide Wire*, the *LumiGuide Equipment R2.0* and the *LumiGuide 3D Hub* is considered substantially equivalent to the AltaTrack system containing the AltaTrack Guidewire, the AltaTrack Equipment R1.2 and the AltaTrack 3D Hub in terms of safety and effectiveness.

Summary of Clinical Performance Data:

Substantial equivalence of the LumiGuide system containing the *LumiGuide Wire*, the *LumiGuide Equipment R2.0* and the *LumiGuide 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 device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion:	The LumiGuide system containing the *LumiGuide Wire,* the *LumiGuide Equipment R2.0* and the *LumiGuide 3D Hub* is considered substantially equivalent to the AltaTrack system containing, the AltaTrack Guidewire, the AltaTrack Equipment R1.2 and the AltaTrack 3D Hub.