



October 24, 2025

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

Re: K252645

Trade/Device Name: LumiGuide Equipment R2.1; LumiGuide Wire; LumiGuide 3D Hub  
Regulation Number: 21 CFR 870.1425  
Regulation Name: Programmable Diagnostic Computer  
Regulatory Class: Class II  
Product Code: DQK, DQX  
Dated: August 21, 2025  
Received: August 21, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for **MARCO CANNELLA -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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252645

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Please provide the device trade name(s).

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LumiGuide Equipment R2.1;  
LumiGuide Wire;  
LumiGuide 3D Hub

Please provide your Indications for Use below.

?

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

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

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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:** 21 August 2025  
**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  
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**Devices:** LumiGuide system, containing the following primary devices:

Trade Name: LumiGuide Equipment R2.1  
 Classification Name: Programmable diagnostic computer  
 Classification Regulation: 21 CFR, Part 870.1425  
 Device Class: II  
 Product Code: DQK

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

**Predicate Devices:** LumiGuide system (K233853), containing the following primary devices:

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 Wire

Classification Name:	Catheter guide wire
Classification Regulation:	21 CFR, Part 870.1330
Device Class:	II
Product Code:	DQX
Trade Name:	LumiGuide 3D Hub
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 Equipment R2.1* 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 R2.1 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 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 R2.1 using FORS technology.

The *LumiGuide 3D Hub* is a sterile, single use accessory to the LumiGuide Equipment R2.1 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 R2.1 enables real time 3D visualization of the connected endovascular catheter.

**Indications for Use:** 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 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 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 *LumiGuide Equipment R2.1* has the same technological characteristics as its predicate, *LumiGuide Equipment R2.0*.

As there are no significant changes to the *LumiGuide Wire* and the *LumiGuide 3D Hub* since the previous 510(k), K233853, their technological characteristics remain the same as those of their previous versions.

**Summary of Non-Clinical Performance Data:**

The testing for the *LumiGuide Equipment R2.1* has been performed according to the applicable international and FDA recognized consensus standards. The test results demonstrate that the *LumiGuide Equipment R2.1* meets the acceptance criteria and is adequate for its intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated and that the overall residual risk is acceptable.

The test evidence generated for the *LumiGuide Wire* and *LumiGuide 3D Hub* in this abbreviated 510(k) submission is based on testing performed according to the applicable international and FDA recognized consensus standards. The test evidence demonstrates that the *LumiGuide Wire* and *LumiGuide 3D Hub* meet the acceptance criteria and are adequate for their intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated and that the overall residual risk is acceptable.

Therefore, the *LumiGuide* system containing the *LumiGuide Equipment R2.1*, the *LumiGuide Wire* and the *LumiGuide 3D Hub* is considered substantially equivalent to the *LumiGuide* system containing the *LumiGuide Equipment R2.0*, the *LumiGuide Wire* and the *LumiGuide 3D Hub* in terms of safety and effectiveness.

**Summary of Clinical Performance Data:**

Substantial equivalence of the *LumiGuide* system containing the *LumiGuide Equipment R2.1*, the *LumiGuide Wire* 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 devices is substantially equivalent to the predicate devices.

**Substantial Equivalence Conclusion:**

The *LumiGuide* system containing the *LumiGuide Equipment R2.1*, the *LumiGuide Wire* and the *LumiGuide 3D Hub* is considered substantially equivalent to the *LumiGuide* system containing the *LumiGuide Equipment R2.0*, the *LumiGuide Wire* and the *LumiGuide 3D Hub*.