October 28, 2025

Volcano Corporation (dba Philips Image Guided Therapy Device)
Aaron Niklaus
Sr. Regulatory Affairs Specialist
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K253399
Trade/Device Name: Visions® PV .014P RX Digital IVUS Catheter;
Visions® PV .018 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: September 30, 2025
Received: September 30, 2025

Dear Aaron Niklaus:

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) 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

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)*
K253399

Device Name
Visions® PV .014P RX Digital IVUS Catheter;
Visions® PV .018 Digital IVUS Catheter

Indications for Use *(Describe)*

Visions® PV.014P RX Digital IVUS Catheter:
The Visions® PV.014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in the cerebral vessels.

The Visions® PV.014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Visions® PV .018 Digital IVUS Catheter:
The Visions® PV .018 Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Visions® PV .018 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PV Digital IVUS Catheter 510(k) Summary
K253399

Sponsor:	Volcano Corporation (dba Philips Image Guided Therapy Devices) Valley Centre Dr #500, San Diego, CA 92130
Contact/Submitter:	Aaron Niklaus Senior Regulatory Affairs Specialist Valley Centre Dr #500, aaron.niklaus@philips.com 651-968-7960
Date of Submission:	09-30-2025

Subject Device 1

Trade Name	Visions® PV.014P RX Digital IVUS Catheter
Common Name	Diagnostic Intravascular Catheter Diagnostic Ultrasound Transducer
Class	2
CFR Numbers	21 CFR 870.1200 Diagnostic Intravascular Catheter 21 CFR 892.1570 Diagnostic Ultrasound Transducer
Product Codes	OBJ, ITX
Panel:	Cardiovascular

Subject Device 2

Trade Name	Visions PV .018 Digital IVUS Catheter
Common Name	Diagnostic Intravascular Catheter Diagnostic Ultrasound Transducer
Class	2
CFR Numbers	21 CFR 870.1200 Diagnostic Intravascular Catheter 21 CFR 892.1570 Diagnostic Ultrasound Transducer
Product Codes	OBJ, ITX
Panel:	Cardiovascular

Predicate Device 1:

Trade Name	Visions® PV .014P RX Digital IVUS Catheter
Common Name	Diagnostic Intravascular Catheter Diagnostic Ultrasound Transducer
Class	2
CFR Numbers	21 CFR 870.1200 Diagnostic Intravascular Catheter 21 CFR 892.1570 Diagnostic Ultrasound Transducer
Product Codes	OBJ, ITX
Panel:	Cardiovascular
510(k) Number	K152829
Clearance Date	11/19/2015

Predicate Device 2:

Trade Name	Visions PV .018 Digital IVUS Catheter
Common Name	Diagnostic Intravascular Catheter Diagnostic Ultrasound Transducer
Class	2
CFR Numbers	21 CFR 870.1200 Diagnostic Intravascular Catheter 21 CFR 892.1570 Diagnostic Ultrasound Transducer
Product Codes	OBJ, ITX
Panel:	Cardiovascular
510(k) Number	K150442
Clearance Date	09/04/2015

Device Description:

The Visions® PV .014P RX Digital IVUS Catheter and the Visions® PV .018 PV .018 Digital IVUS Catheter are being bundled into one submission per FDA Guidance for Industry: Bundling Multiple Devices or Multiple Indications in a Single Submission, June 2007 (FDA-2003-D-0376), as the two catheters share the same indications for use, FDA classification product codes, and technological characteristics, and part of the same product line of catheters.

Visions® PV .014P RX Digital IVUS Catheter
The Visions® PV .014P RX Digital IVUS Catheter incorporates a cylindrical ultrasound transducer array located near the distal tip of the catheter. The array radiates acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary or peripheral vessels.

The Visions® PV .014P RX Digital IVUS Catheter utilizes an internal lumen that allows the catheters to track over a 0.018" (0.46 mm) guide wire. The guide wire exits from the guide wire lumen approximately 31 cm proximal to the catheter tip. The PV .018 catheters are introduced either percutaneously or via surgical cut down into the vascular system.

The Visions® PV .014P RX Digital IVUS Catheter may only be used with Volcano imaging systems, such as the Volcano s5™, Volcano s5i™, Volcano CORE Mobile, and Volcano CORE imaging systems. The catheter will not operate if connected to any other imaging system.

Visions® PV .018 Digital IVUS Catheter
The Visions® PV .018 Digital IVUS Catheter incorporates a cylindrical ultrasound transducer array located near the distal tip of the catheter. The array radiates acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is used to generate real-time images of the coronary or peripheral vessels.

The Visions® PV .018 Digital IVUS Catheter utilizes an internal lumen that allows the catheters to track over a 0.018" (0.46 mm) guide wire. The guide wire exits from the guide wire lumen approximately 31 cm proximal to the catheter tip. The PV .018 catheters are introduced either percutaneously or via surgical cut down into the vascular system.

The Visions® PV .018 Digital IVUS Catheter may only be used with Volcano imaging systems, such as the Volcano s5™, Volcano s5i™, Volcano CORE Mobile, and Volcano CORE imaging systems. The catheter will not operate if connected to any other imaging system.

Indications For Use:

Visions® PV .014P RX Digital IVUS Catheter
The Visions® PV.014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in the cerebral vessels.

The Visions® PV.014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Visions® PV .018 Digital IVUS Catheter
The Visions® PV .018 Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a crosssectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Visions® PV .018 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Substantial Equivalence

Intended Use

The Intended Use of the Subject Devices are the same as their respective Predicate Devices.

Technological Characteristics

The Subject Devices have the same technological characteristics as their respective Predicate Devices with no significant updates to device design, specification, or performance. The Instructions for Use (IFU) have been updated to add a new Precaution. This Precaution is the result of cases where physicians, during "radial-to-peripheral" procedures (radial access), have used a Digital IVUS Catheter without the appropriate sheath and/or guide catheter; this inappropriate use could lead to failure to provide adequate support for maneuvering the guidewire and catheter to peripheral vessels. The Precaution is intended to ensure that physicians use a guide sheath of appropriate length to prevent inadequate support for maneuvering the guidewire and catheter to peripheral vessels.

The modifications made to the Visions® PV .014P RX Digital IVUS Catheter and Visions® PV .018 Digital IVUS Catheter (do not affect the intended use of the device or technological characteristics. The indications for use are identical to those of the currently marketed predicate devices (Visions® PV .014P RX Digital IVUS Catheter and Visions PV.018 Digital IVUS Catheter cleared under K150442). The Subject Devices are substantially equivalent to their respective legally marketed Predicate Devices.

Performance Data
No performance testing was completed to support this 510(k) Submission.

Conclusion

Both Subject Devices have the same Intended Use and Technological Characteristics as their respective Predicate Devices, demonstrating Substantial Equivalence.