October 28, 2026

Evident Vascular, Inc.
Angela Frederickson
President, Principal RAQA Consultant
Sparq Compliance
2624 Wagner Pl.
El Dorado Hills, California 95762

Re: K261648
Trade/Device Name: Evident Vascular™ Guidance System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, OBJ, ITX
Dated: September 28, 2026
Received: September 28, 2026

Dear Angela Frederickson:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARCO CANNELLA -S

Marco Cannella, Ph.D.
Acting 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.	K261648

Please provide the device trade name(s).

Evident Vascular Guidance System (EVGS-001)

Please provide your Indications for Use below.

The Evident Vascular Guidance System (EVGS) is intended for ultrasound examination of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

The Evident Peripheral Imaging Catheters generate ultrasound images and are intended for ultrasound examination of peripheral vascular pathology only.

The recommended use of each of these catheters may vary depending on the size and type of catheter. Refer to the Instructions for Use for all Evident Peripheral Imaging Catheters for additional information on recommended use.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary – [21 CFR 807.92]

807.92(a)(1), (2), (3)

Date Prepared:	October 28, 2026
Submitter Name:	Evident Vascular, Inc. 142 Charcot Avenue San Jose, CA 95131 +1 (408) 785-6511
Official Correspondent:	Angela Frederickson, Principal RAQA Consultant Sparq Compliance +1 (650) 336-3887 angela.frederickson@evidentvascular.com
Device Trade Name:	Evident Vascular™ Guidance System
Common Name:	Ultrasound Imaging System
Review Panel:	Office of Health Technology: Cardiac Electrophysiology, Diagnostics, and Monitoring (OHT2A)
Classification Name:	Ultrasonic Pulsed Echo Imaging System Ultrasonic Diagnostic Transducer Intravascular Ultrasound Catheter
Regulation No.:	892.1560 892.1570 870.1200
Classification Code:	IYO ITX OBJ
Predicate Device:	**iLab Polaris Multi-Modality Guidance System**: K210889 Classification Code: DQK, DSK, IYO, ITX Regulation: 21 CFR 870.1425,
Reference Device:	**OptiCross 18 Peripheral Imaging Catheter**: K222568 Classification Code: ITX, OBJ Regulation: 892.1570, 870.1200
Reference Device:	**OptiCross 18 Peripheral Imaging Catheter**: K200733 Classification Code: ITX, OBJ Regulation: 892.1570, 870.1200

Device Description: *807.92(a)(4)*

The Evident Vascular™ Guidance System (EVGS) is designed for ultrasound examinations of intravascular pathology. The EVGS supplies diagnostic information when used in conjunction with the Evident Peripheral Imaging Catheters during intravascular ultrasound (IVUS) imaging of peripheral vasculature. It is designed to be used as an adjunct to conventional angiographic procedures or endovascular therapy.

The system includes the workstation computer that is the main system controller and runs dedicated software. A single-use, sterile intravascular ultrasound catheter generates real-time IVUS images, which are displayed on a user interface tablet. The Evident™ Tablet serves as the primary user interface image visualization and system control. The Catheter Interface Module (CIM) provides the connection to the catheter. An optional auxiliary display may be used with the workstation for additional image viewing, depending on clinical preference.

The EVGS is available in both a mobile cart configuration and an integrated laboratory configuration. Both configurations provide the same system functionality and user interface capabilities, with differences limited to installation environment and system layout.

Indications for Use/Intended Use: *807.92(a)(5)*

The Evident Vascular™ Guidance System (EVGS) is intended for ultrasound examination of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

The Evident™ Peripheral Imaging Catheters generate ultrasound images and are intended for ultrasound examination of peripheral vascular pathology only.

The recommended use of each of these catheters may vary depending on the size and type of catheter. Refer to the Instructions for Use for all Evident Peripheral Imaging Catheters for additional information on recommended use.

Technological Characteristics: *807.92(a)(6)*

The Evident Vascular™ Guidance System (EVGS) includes a Console featuring a workstation, catheter interface module (CIM), tablet-based user interface, and single-use intravascular ultrasound (IVUS) imaging catheters. The system is intended as an adjunct to angiographic procedures or endovascular therapy for examination of intravascular pathology EVGS provides real-time intravascular ultrasound imaging of the peripheral vasculature.

The EVGS and the predicate device share the same fundamental IVUS imaging modality and intended diagnostic purpose of intravascular ultrasound imaging.

Both systems are available in integrated and mobile configurations and provide comparable imaging functionality. Each system complies with applicable safety and electromagnetic compatibility requirements.

The EVGS user interface incorporates touch-screen operation and optional voice-control functionality. The system provides a secure connection between the catheter and console that supports substantially equivalent imaging performance and does not change the intended use or risk profile.

The predicate device includes additional functionality and broader indications not present in the EVGS, including Fractional Flow Reserve (FFR), Diastolic hyperemia-Free Ratio (DFR), and automatic pullback functionality. EVGS does not provide FFR, DFR, or automatic pullback capabilities. In addition, the Evident Peripheral Imaging Catheters are indicated for ultrasound examination of peripheral vascular pathology only.

These differences represent a narrowing of the subject device's functionality and catheter indications relative to the predicate and do not raise different questions of safety or effectiveness as the EVGS retains the same fundamental IVUS imaging technology, operating principles, and intended diagnostic purpose while excluding these additional functions.

The Evident imaging catheters and the reference catheters use similar intravascular ultrasound technology and share comparable fundamental design characteristics. The catheters are provided sterile and meet biocompatibility requirements for limited-exposure, blood-contacting devices.

Differences between the subject and reference catheters relate to implementation details that do not affect the fundamental operating principle, intended use, or performance characteristics. These differences do not raise new or different questions of safety or effectiveness.

Summary of Non-Clinical Test - Performance and Safety Testing: *807.92(b)(1)*

FDA guidance *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (February 21, 2023), applicable to product codes IYO and ITX, was followed in the

evaluation of the Evident Vascular™ Guidance System (EVGS). The system was assessed for performance, biocompatibility, electrical safety, electromagnetic compatibility, and acoustic output, and was found to meet applicable requirements.

FDA guidance *Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters* (April 14, 2023) was applied to the Evident Vascular Peripheral Imaging catheters for particulate and coating characterization. The catheters met the testing and performance expectations outlined in the guidance and associated standards. Design verification testing was conducted to confirm that system performance met design input requirements under simulated benchtop use conditions. Relevant requirements from the ultrasound and PTA guidance documents were applied as part of this evaluation.

The patient-contacting materials of the imaging catheters meet the biocompatibility requirements of ISO 10993-1 for limited-exposure, external-communicating, circulating blood devices. Biocompatibility testing was performed in alignment with FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Sept. 8, 2023* was also consulted.

Human factors validation testing was performed in accordance with FDA's Applying Human Factors and Usability Engineering to Medical Devices (2016). Testing demonstrated that intended users can safely and effectively perform critical tasks associated with EVGS setup, catheter preparation, imaging, and system operation. Software verification and validation testing for the EVGS was conducted in accordance with FDA guidance Content of Premarket Submissions for Device Software Functions and IEC 62304. Testing demonstrated that the software performs as intended across supported system configurations and does not raise new issues of safety or effectiveness compared to
the predicate device.

Cybersecurity testing performed in accordance with FDA's *Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*
(September 2023), demonstrated that the EVGS architecture, access controls, data handling, and network interfaces meet applicable cybersecurity expectations.

EVGS meets the requirements of the applicable elements of the following safety and EMC standards.

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2021 - *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
- ANSI/AAMI/IEC 60601-1-2:2014/A1:2021 - *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbances – Requirements and tests.*

- IEC 60601-2-37:2024 - *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.*
- IEC/TS 60601-4-2:2024 - *Medical Electrical Equipment – Part 4-2: Guidance and Interpretation – Electromagnetic Immunity: Performance of Medical Electrical Equipment and Medical Electrical Systems.*
- ANSI/USEMCSC C63.27-2021 - *Wireless Coexistence*
- FCC 47 CFR Part 15, Subpart C - *Intentional Radiators, Subpart E: Unlicensed National Information Infrastructure Device*

Summary of Clinical Tests: *807.92(b)(2)*

Clinical performance testing was not conducted.

Conclusion: *807.92(b)(3)*

Based on a comparison of intended use, operating principles, and fundamental technological characteristics, together with non-clinical performance verification and validation, the Evident Vascular™ Guidance System (EVGS) is substantially equivalent to the predicate device, the iLab™ Polaris Multi-Modality Guidance System. A comparison of the subject and predicate devices, including performance testing of the EVGS console and catheters, supports a determination of substantial equivalence and does not raise new or different questions of safety or effectiveness.