June 15, 2026

Luma Vision Limited
Marta Walker
Director of Quality and Regulatory at Luma Vision
Block C, Parkview House-Beech Hill Office Campus
Beech Hill Rd.
Dublin, D04 K5D0
Ireland

Re: K260885
Trade/Device Name: VERAFEYE Imaging and Guidance System (VF-VIS-002)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, DQK
Dated: March 17, 2026
Received: March 17, 2026

Dear Marta Walker:

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 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 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

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.	K260885

Please provide the device trade name(s).

VERAFEYE Imaging and Guidance System (VF-VIS-002)

Please provide your Indications for Use below.

The VERAFEYE Imaging and Guidance System is intended for cardiac applications. The system provides 2D & 3D images of the heart, cardiac valves, great vessels, and surrounding anatomical structures for the evaluation of the presence or absence of pathology.

The VERAFEYE Imaging and Guidance System is also intended for catheter-based cardiac electrophysiological (EP) procedures in the Left and Right Atrium. The VERAFEYE Imaging and Guidance System provides the reconstruction of chamber geometry from ultrasound data, and visualization of the chamber anatomy and intracardiac catheter location during procedures.

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)

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section- K260885

510(k) Summary of Safety and Effectiveness Information
as required by section 21 CFR 807.92

Submitter of 510(k)

Manufacturer Name:	Luma Vision Limited
Address:	Block C, Parkview House, Beech Hill Office Campus, Beech Hill Road, Dublin D04 K5D0, Ireland
Contact Person:	Marta Walker
Phone:	0031680132668
Email:	marta.walker@lumavision.com
Job Title:	Quality Assurance & Regulatory Affairs Director
Date Prepared:	15th June 2026

Traditional 510(k) Submission for VERAFEYE Imaging and Guidance System

Device Information:

Trade / Proprietary Name:	VERAFEYE Imaging and Guidance System (VF-VIS-002)
Common / Usual Name:	VERAFEYE Imaging and Guidance System
Device:	System, Imaging, Pulsed Echo, Ultrasonic
Regulation Description:	Ultrasonic Pulsed Echo Imaging System
Regulation Number:	21 CFR §892.1560
Device Classification:	Class II
Product Code:	IYO, DQK

Panel: Division of Cardiovascular Devices

Predicate & Reference Devices:

Primary Predicate Device: *(K242893)*

Trade / Device Name: VERAFEYE Imaging System (VF-VIS-001)
Regulation Number: 21 CFR §892.1560
Regulatory Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO

Secondary Predicate Device: *(K251234)*

Trade / Device Name: EnSite™ X EP System
Regulation Number: 21 CFR §870.1425
Regulatory Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK

Device Description

The **VERAFEYE Imaging and Guidance System** is a non-sterile, reusable ultrasound imaging and guidance system intended for use in a cardiac catheterization laboratory for adult cardiac applications. The system consists of a System Console with integrated computing hardware and software, a Catheter Interface Unit (CIU), a three-dimensional electromagnetic tracking subsystem, a pulse phase (ECG) module, and an ablation interface for compatibility with third-party ablation catheters. An itemization of the components is provided in the following table.

Component	**Model No.**	**Sub-component**	**Patient Contact Material**
Catheter Interface Unit	VF-CIU-002	N/A	N/A
System Console	VF-SC-002	Sensor Interface Unit	N/A
		System Control Unit	N/A
		Window Field Generator	N/A
		Window Field Generator Bracket	N/A
		Pulse Phase Module	N/A
		Reference Sensor	N/A
		Pulse Phase Module Leads	Thermoplastic Polyurethane (TPU)
	3M™ Red Dot™ Model 2560 or 2570	Pulse Phase Module Electrode, single use	Thermoset Polyurethane
	DE-009c	Reference Sensor Patch, single use	Medical grade acrylic
	60-860 – CIV-Flex™ probe cover	Reference Sensor Sheath, single use	Medical grade acrylic
Ablation Interface	VF-ABI-001	Ablation Interface	N/A

No part of the VERAFEYE Imaging and Guidance System is provided sterile.

The system transmits ultrasound energy into adult patients to generate real-time two-dimensional (B-mode) and three-dimensional volumetric images of the heart, cardiac valves, great vessels, and surrounding anatomical structures for evaluation of the presence

or absence of pathology. It provides scale indication with respect to anatomical structures to support clinical assessment in conjunction with other medical information.

The system utilizes compatible intracardiac imaging catheters intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices within the heart. The system receives ultrasound and tracking signals from the imaging catheter as well as supported third-party ablation catheters, converts analog signals to digital data, processes imaging information, and displays reconstructed chamber geometry and catheter position to assist clinicians during electrophysiology and other percutaneous cardiac procedures. The catheter is intended for imaging guidance only and not for treatment delivery.

The principle of operation for the imaging aspects of the VERAFEYE Imaging and Guidance System is the same as that for commonly used ultrasound imaging systems (both external and intra-operative). To localize the imaging information with respect to the anatomy and anatomical structures i.e. the navigational aspect of the VERAFEYE Imaging and Guidance System, magnetic pose sensors are incorporated adjacent to the ultrasound transducer of the VERAFEYE Imaging Catheter. The pose sensors utilize electrical coils in which signals are induced when placed in a moving electromagnetic (EM) field; the signals are indicative of the position and orientation of the coil within the moving EM field. The pose sensors allow for the pose of the tip, and therefore the imaging plane, to be known with respect to the EM field generator. The image data, tracking information and heartbeat signal information allow for the reconstruction of the relevant anatomical chambers, in order to provide global orientation for navigation along with live 2D and 4D ultrasound imaging. For compatible third-party ablation catheters, the same principle of EM tracking of the catheter tip is used to display the live pose of the device within the anatomical chamber data.

The primary responsibility of the software is to control the hardware for signal acquisition (ultrasound system, motor, EM tracking system and ECG interface), acquire the digitized signals into B-mode images and/or volumes and present them to the user. Based on that data the user can create semantic landmarks like the left/right atrium. The imaging catheter and, if connected, the third-party ablation catheter are shown in relation to the imaging, volumes and/or landmarks. Auxiliary functions are screenshot and video clip recording as well as recording export to external USB devices.

The tracking of the imaging catheter as well as the optional, supported third-party ablation catheter is done via EM tracking. The catheters contain sensor(s) which are within an EM field generated by a field generator. The EM tracking system digitizes the pose (3D position

and orientation) which then is used by the software to show the catheters relative to the global anatomical orientation.

Performance Characteristic	System Capability
2D B-mode image resolution	0.5mm
Tracking positional accuracy	3mm
Tracking orientation accuracy	5°
Intra-volume point to point accuracy	5mm @ 2cm depth
Combined volume accuracy	3mm
Image acquisition frequency	20Hz
Tracking frequency	30Hz

The intended use environment for the VERAFEYE Imaging and Guidance System is a cardiac catheter laboratory (cath lab), a minimally invasive operating environment designed for cardiac procedures. The workspace is centered around an adjustable patient bed integrated with a C-arm X-ray system, enabling fluoroscopic imaging while requiring staff to wear protective lead equipment. The operating room includes ECG monitoring, ceiling-mounted display panels, and imaging systems such as fluoroscopy, echocardiography (including TEE and ICE), and advanced technologies like electro-anatomical mapping and ablation guidance. Ambient noise levels typically range from 50–65 dBA, while lighting is adjusted throughout procedures to support patient preparation, vascular access, and image-guided interventions. The cath lab is divided into sterile and non-sterile zones, with the sterile area extending from the patient bed to the patient's abdomen. Clinical staff, equipment, and workspaces within this boundary must maintain sterility to ensure patient safety and support efficient procedural workflows.

Intended Use: Cardiac

Indications for Use:

The VERAFEYE Imaging and Guidance System is intended for cardiac applications. The system provides 2D & 3D images of the heart, cardiac valves, great vessels, and surrounding anatomical structures for the evaluation of the presence or absence of pathology.

The VERAFEYE Imaging and Guidance System is also intended for catheter-based cardiac electrophysiological (EP) procedures in the Left and Right Atrium. The VERAFEYE Imaging and Guidance System provides the reconstruction of chamber geometry from ultrasound data, and visualization of the chamber anatomy and intracardiac catheter location during procedures.

Indications for Use Discussion

The intended use of the VERAFEYE Imaging and Guidance System combines functionalities from the 2 predicate devices without introducing a new/modified clinical purpose, patient population, or therapeutic indication that could impact safety or effectiveness.

Similar to the Primary Predicate Device (VERAFEYE Imaging System), the system provides 2D and 3D imaging of cardiac anatomy for evaluation of the presence or absence of pathology. Similar to the Secondary Predicate Device (EnSite X EP System), it supports electrophysiology (EP) procedures by providing visualization of the chamber anatomy and intracardiac catheter location. The chamber geometry reconstruction function is derived from ultrasound imaging data and serves as an anatomical guidance tool during EP procedures.

The VERAFEYE Imaging and Guidance System remains limited to diagnostic imaging and procedural guidance within the heart and does not deliver therapy or perform autonomous clinical decision-making. The proposed intended use represents an integration of established imaging and electrophysiology guidance capabilities rather than a change in the clinical purpose or risk profile.

Functional and Technological Comparison

The VERAFEYE Imaging and Guiding System (VF-VIS -002) adds the following functionalities to the VERAFEYE Imaging System (VF-VIS-001):

1. Creation of anatomical models of the left and right atria.
2. Real-time display of the position of the imaging catheter and supported ablation catheters. (Note: VF-VIS-002 supports the Abbott FlexAbility and TactiCath ablation catheters)
3. Allow the user to place markers on the anatomical models that signal locations that have been ablated (ablation markers).

Table 1 below provides a functional and technological comparison between the VERAFEYE Imaging and Guidance System VF-VIS-002 and the legally marketed predicate devices, VERAFEYE Imaging System VF-VIS-001 (K242893) and EnSite™ X EP System (K251234).

As shown in Table 1, the subject device has the same intended use, classification, and similar technological characteristics as the predicate devices.

Consistent with the VERAFEYE Imaging System predicate, the subject device is intended for cardiac applications and provides two-dimensional (B-mode) and three-dimensional ultrasound images of the heart, cardiac valves, great vessels, and surrounding anatomical

structures to evaluate the presence or absence of pathology, and to provide scale information that may be used adjunctively with other medical data for clinical diagnosis.

Consistent with the EnSite™ X EP System predicate, the subject device is also intended for catheter-based cardiac electrophysiology procedures and provides visualization of intracardiac catheter location and reconstruction of chamber geometry to support electrophysiology diagnostics and monitoring.

Together, the predicate devices represent the full scope of ultrasound imaging and electrophysiology guidance functions of the VERAFEYE Imaging and Guidance System VF-VIS-002.

Table 1. Predicate Device Comparison Table- VERAFEYE Imaging and Guidance System

Substantial Equivalence Imaging and Guidance System

Description	Predicate Device 1	*Predicate Device 2*		
Manufacturer	VERAFEYE Imaging System VF-VIS-001 **K#** K242893	EnSite™ X EP System **K#** K251234	VERAFEYE Imaging and Guidance System VF-VIS-002 **K#** K260885	Discussion of Equivalence & Differences
Classification	Class II	Class II	Class II	Same as both predicate devices
Regulation:	21 CFR 892.1560 – IYO	21 CFR 870.1425- DQK	21 CFR 892.1560 – IYO 21 CFR 870.1425- DQK	Same as both predicate devices
Regulation Name	IYO - Ultrasonic pulsed echo imaging system.	DQK- Programmable diagnostic computer.	IYO - Ultrasonic pulsed echo imaging system. DQK- Programmable diagnostic computer.	Same as both predicate devices
Product Code	IYO	DQK	IYO, DQK	Same as both predicate devices
Intended Use Environment	Cardiac - Intracardiac Echocardiography	Cardiac Electrophysiology, Diagnostics, and Monitoring Devices	*Cardiac Electrophysiology - Intracardiac Echocardiography*	Applicable indications taken from both predicates;

Description	Predicate Device 1	*Predicate Device 2*		
Manufacturer	VERAFEYE Imaging System VF-VIS-001 **K#** K242893	EnSite™ X EP System **K#** K251234	VERAFEYE Imaging and Guidance System VF-VIS-002 **K#** K260885	Discussion of Equivalence & Differences
				ICE from Device 1 & Electrophysiology from Device 2
Indications for Use	The VERAFEYE Imaging System is intended for cardiac applications. The system transmits ultrasound energy into adult patients creating 2D (B-mode), & 3D images of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system also provides the ability to indicate scale with respect to anatomical structures, which provides information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The system utilizes catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other	The EnSite X EP System is a suggested diagnostic tool in patients for whom electrophysiology studies have been indicated. The EnSite X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological procedures	The VERAFEYE Imaging and Guidance System is intended for cardiac applications. The system provides 2D & 3D images of the heart, cardiac valves, great vessels, and surrounding anatomical structures for the evaluation of the presence or absence of pathology. The VERAFEYE Imaging and Guidance System is also intended for catheter-based cardiac electrophysiological (EP) procedures in the Left and Right Atrium. The VERAFEYE Imaging and Guidance System provides the reconstruction of chamber geometry from ultrasound data, and visualization of the chamber anatomy and intracardiac catheter location during procedures.	Equivalent to features prescribed in both – see note *1

Description	Predicate Device 1	*Predicate Device 2*		
Manufacturer	VERAFEYE Imaging System VF-VIS-001 **K#** K242893	EnSite™ X EP System **K#** K251234	VERAFEYE Imaging and Guidance System VF-VIS-002 **K#** K260885	Discussion of Equivalence & Differences
	devices in the heart of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.			
Operating Frequency	*5.25MHz*	*N/A*	*5.25MHz*	Same as predicate Device 1
Modes	*2D (B-mode) and 3D*	*N/A*	*2D (B-mode) and 3D*	Same as predicate Device 1
Transducers/catheters:	*VERAEYE ICE Catheter VF-VIC-001*	*N/A*	*VERAEYE ICE Catheter VF-VIC-002*	Same as predicate Device 1 & compatible catheter
System Features				
Cardiac Measurements and Calculations	*Yes: Length & area*	*N/A*	*Yes: Length & area*	Same as predicate Device 1
Cybersecurity Features	*yes*	*N/A*	*yes*	Same as Device 1
Local user accounts with user authentication & authorization	*yes*	*N/A*	*yes*	Same as predicate Device 1
Table side Remote Control:	*The VERAFEYE ultrasound imaging system will provide control options through mouse and keyboard*	*N/A*	*The VERAFEYE ultrasound imaging system will provide control options through mouse and keyboard*	Same as predicate Device 1
Service Save logs:	*yes*	*N/A*	*yes*	Same as predicate Device 1
Security Hot-fix Installation:	*Yes: Through USB drive*	*N/A*	*Yes: Through USB drive*	Same as predicate Device 1

Description	Predicate Device 1	*Predicate Device 2*		
Manufacturer	VERAFEYE Imaging System VF-VIS-001 **K#** K242893	EnSite™ X EP System **K#** K251234	VERAFEYE Imaging and Guidance System VF-VIS-002 **K#** K260885	Discussion of Equivalence & Differences
Study Back-up and Restore:	*yes*	*N/A*	*yes*	Same as predicate Device 1
Output Display Standard (Track 3):	*yes*	*N/A*	*yes*	Same as predicate Device 1
Patient Contact Materials:	*yes*	*N/A*	*yes*	Same as predicate Device 1
Motor Unit:	*Motor Unit – VERAFEYE system*	*N/A*	*Motor Unit – VERAFEYE system*	Same as Device 1
	Function: Rotates the inner part of the catheter NOTE: The motor unit, is equivalent of the motor unit of the Ultra ICE Plus catheter (# K181042) – we can take this part of that product as a reference device, as although it has a different intended use (for the entire Ultra ICE catheter than VERAFEYE, the "motor unit" part of the Ultra ICE catheter is equivalent operational principle (rotates) to the VERAFEYE motor unit as their intended use is to rotate the catheter and to	*N/A*	*Function: Rotates the inner part of the catheter NOTE: The motor unit, is equivalent of the motor unit of the Ultra ICE Plus catheter (# K181042) – we can take this part of that product as a reference device, as although it has a different intended use (for the entire Ultra ICE catheter than VERAFEYE, the "motor unit" part of the Ultra ICE catheter is equivalent operational principle (rotates) to the VERAFEYE motor unit as their intended use is to rotate the catheter and to convert signals into imaging.*	Same as predicate Device 1

Description	Predicate Device 1	*Predicate Device 2*		
Manufacturer	VERAFEYE Imaging System VF-VIS-001 **K#** K242893	EnSite™ X EP System **K#** K251234	VERAFEYE Imaging and Guidance System VF-VIS-002 **K#** K260885	Discussion of Equivalence & Differences
	convert signals into imaging.			

*Note *1- The proposed intended use of the VERAFEYE Imaging and Guidance System is acceptable because it combines functionalities from the 2 predicate devices without introducing a new/modified clinical purpose, patient population, or therapeutic indication that could impact safety or effectiveness. Similar to the Primary Predicate Device (VERAFEYE Imaging System), the system provides 2D and 3D imaging of cardiac anatomy for evaluation of the presence or absence of pathology. Similar to the Secondary Predicate Device (EnSite X EP System), it supports electrophysiology (EP) procedures by providing visualization of the chamber anatomy and intracardiac catheter location. The chamber geometry reconstruction function is derived from ultrasound imaging data and serves as an anatomical guidance tool during EP procedures. The VERAFEYE Imaging and Guidance System remains limited to diagnostic imaging and procedural guidance within the heart and does not deliver therapy or perform autonomous clinical decision-making. The proposed intended use represents an integration of established imaging and electrophysiology guidance capabilities rather than a change in the clinical purpose or risk profile*

Non-clinical Performance testing

Non-clinical performance testing to substantiate the effectiveness of the VERAFEYE Imaging and Guidance System encompasses the requirements pertaining to Imaging & Guidance, Operating Environment, Clinical workflow and Lifetime. The specific tests are summarized in the table below.

Clinical data was not utilized to demonstrate safety or effectiveness of the VERAFEYE Imaging and Guidance system.

Test Category	Performance trait evaluated	Enabled function
Imaging and guidance	- Field of View - Imaging geometry - Image resolution - Dynamic range - Point to point accuracy - Roll accuracy - Device pose accuracy - Temporal accuracy	The system is able to provide images suitable for the visualization of 3rd party devices & cardiac anatomy. It also provides continuous tracking data with respect to the position of the catheter and compatible 3rd party therapy devices
Operating environment	- Thermal index - Mechanical index - Acoustic output - Surface temperature - Emissions & dielectric strength	3D imaging is provided while remaining compliant with the standards for acoustic output for cardiac devices

Clinical workflow	- Spatial map display & control, - Operational latency physiological signals monitoring - Third party tool representation	Operation of the system can be achieved within the normal flow of the electrophysiology procedure
Lifetime	- System runtime - Expected service life	The function of the system is maintained consistent with the length of electrophysiology procedures
Software	Software verification at unit, integration and system level	Live imaging, creation and display of anatomical maps, tracking of the image & third party ablation catheter & export of recorded data.
Design validation	- Pre-clinical - Summative	Operation of the system conforms with the clinical workflow in a simulated use environment

There are no technological difference between the subject device and predicate device 1. The technological differences between the subject device and predicate device 2 stem from the generation of the displayed cardiac maps. For the subject device, the maps are generated from application of tracking data to the image data such that a map is created depicting structures that are observable in the ultrasound image. For predicate device 2, the maps are generated from an application of the tracking data to the measured electro-potential data such that the maps that are generated are an illustration of electro-physiologic function. The ability of the subject device to create anatomical maps is a function of ultrasound imaging capability that the system has; predicate device 2 does not incorporate an ultrasound imaging capability.

Conclusion:

The complimentary functions of predicate device 1 and device 2 are combined in the VERAFEYE Imaging and Guidance System. The subject device and predicate devices share common intended use, principles of operation and technological characteristics though all of the features are not present together in either one of the predicates. Predicate device 1 employs technical characteristics and functionality that supports ultrasound image acquisition; predicate device 2 employs technology and functionality that supports the combination of imaging data, tracking data and anatomical map creation. The combination of previously existing but dissimilar technologies into a single platform facilitates mitigation of hazards associated with lack of availability of one of

the technologies. Any hazards arising from combination of normally separated technologies is addressed through compliance with the relevant standards and the appropriate particular standards.

After analyzing the results of the bench, laboratory and electrical safety tests, it can be concluded that the VERAFEYE Imaging and Guidance System and the predicate devices (K242893 and K251234) are substantially equivalent.

The subject device (VERAFEYE Imaging and Guiding System VF-VIS-002) and predicate devices are all intended for use in intravascular and/or intracardiac imaging. The results of the relevant performance data and compatibility testing support a determination that the proposed subject devices do not raise new questions of safety or effectiveness and is substantially equivalent to the predicate devices.