March 24, 2025

Luma Vision Limited
Marta Walker
Quality Assurance & Regulatory Affairs Director
Block C, Parkview House
Beech Hill Office Campus, Beech Hill Road
Dublin, D04 K5D0
Ireland

Re: K242893
Trade/Device Name: VERAFEYE System; VERAFEYE Imaging Catheter & VERAFEYE Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ, IYO
Dated: September 10, 2024
Received: September 23, 2024

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 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242893

Device Name
VERAFEYE System
VERAFEYE Imaging Catheter & VERAFEYE Imaging System

Indications for Use *(Describe)*

VERAFEYE Imaging Catheter

The VERAFEYE Imaging Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.
The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

VERAFEYE Imaging System

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 devices in the heart of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Luma Vision Limited
Block C, Parkview House,
Beech Hill Office Campus,
Beech Hill Road,
Dublin D04 K5D0, Ireland
www.lumavision.com
info@lumavision.com

Department of Health and Human Services
Center for Devices and Radiological Health
Office of Product Evaluation and Quality
Office of Cardiovascular Devices

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@lumavison.com
Job Title:	Quality Assurance & Regulatory Affairs Director
Date Prepared:	22 September 2024

510K Bundle Submission of VERAFEYE Imaging Catheter & VERAFEYE Imaging System

Device Information:

Trade / Proprietary name:	VERAFEYE System
Common / Usual name:	VERAFEYE Imaging Catheter & VERAFEYE Imaging System
Device:	Catheter, Ultrasound, Intravascular
Regulation Description:	*Diagnostic Intravascular Catheter*
Classification:	*21 CFR§870.1200 (OBJ)* - Class II
Device:	System, Imaging, Pulsed Echo, Ultrasonic
Regulation Description:	*Ultrasonic Pulsed Echo Imaging System*
Classification:	*21 CFR§892.1560 (IYO)* - Class II

Panel: *Cardiovascular*

Predicate & Reference Devices:

Primary Predicate Device*: K212959*
Trade/Device Name: ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ

***Secondary Predicate Device**: K211726*

Trade/Device Name: ACUSON SC2000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: OBJ, IYO, IYN, ITX, LLZ

Reference Predicate Devices:

Reference Device: K181042, Ultra ICE Plus – PI 9 MHz Peripheral Imaging Catheter (reference is used to compare to the motor unit only)

Device Description:

The VERAFEYE System is intended to be used for live, minimally-invasive guidance of several different intracardiac procedures including, but not limited to, atrial ablation procedures and transseptal punctures. The system will provide image information of cardiovascular anatomic features, spatial relationships of other devices within the heart and great vessels, physiological information of cardiovascular structures and features. In doing so we expect to provide an imaging system capable of improving the safety, expediency, cost-effectiveness and patient tolerance of the aforementioned procedures compared to the same procedures using the existing technologies and methodologies.

The system will be comprised of a catheter and an ultrasound imaging system with a console and computer screen.

The VERAFEYE Imaging System includes the System Console (SC) for image display and manipulation as well as the Catheter Interface Unit (CIU) which the catheter connects to. The SC will have two monitors to allow for ease of image view and review for both the technician and physician user.

The technician user will be able to control the system software via a graphical user interface using multiple methods of input including a mouse and keyboard. Caster wheels on the SC will allow easy movement of the system throughout the cardiac interventional lab which can have a small footprint as well as small obstacles to cross.

The catheter will be a 11Fr single use, sterile device, which will be able to perform intracardiac and intraluminal ultrasound imaging of adults. The catheter will be capable of live 2D side viewing imaging, as well as live 3D rendered images. The imaging system will be able to resolve and measure features such as the inferior and superior vena cava, ascending and descending aorta, left and right atria, left and right ventricles, fossa ovalis, aortic valve, mitral valve and tricuspid valve.

The physician user will have easy steering maneuverability of the catheter via deflection and rotation, facilitating control over the position of the transducer to allow for multiple angles of images.

Intended Use: Cardiac

Indication for Use*:*

VERAFEYE Imaging Catheter

The VERAFEYE Imaging Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.
The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

VERAFEYE Imaging System

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 devices in the heart of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Functional and Technological Comparison:

Tables 1 below include functional and technological comparison between the VERAFEYE Imaging Catheter *and market cleared ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter, K212959*

Tables 2 include functional and technological comparison between the VERAFEYE Imaging System *and market cleared ACUSON SC2000 Diagnostic Ultrasound System, K211726*

Table 1. Predicate device 1: Medical Device 1: VERAFEYE Imaging Catheter

Medical Device 1	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging Catheter	ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter – # K212959	Comparison
Classification:	Class II	Class II	Same as predicate
Regulation:	21 CFR 870.1200	21 CFR 870.1200	Same as predicate
Regulation Name:	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	Same as predicate
Product Code:	OBJ	OBJ	Same as predicate
Catheter Type:	Intracardiac Echocardiography	Intracardiac Echocardiography	Same as predicate
Intended use:	The VERAFEYE Imaging Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	Same as predicate
Imaging energy:	Ultrasound	Ultrasound	Same as predicate
Acoustic Array:	64 channel (segmented aperture)	192 channel (segmented aperture)	Same as predicate
Insertable Outer Diameter:	11 French (3.7mm)	12.5 French (4.2 mm)	Same as predicate
Insertable Length:	- Total Insertable length: 95cm - Distal Tip: 51mm	- Total Insertable Length: 90 cm - Distal Tip: 30.5mm (1.20”) - Strain Relief: 39.4mm(1.55”)	Same as predicate
Patient Contact Material (Catheter Body):	Nylon (ML21) Pebax 35 & Pebax 55 Polymethyl Pentene (TPX) Silicone (grade 4035)	Pebax series Comply with ISO 10993-1	Same as predicate

Medical Device 1	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging Catheter	ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter – # K212959	Comparison
Minimum Introducer Sheath Requirement:	12 French or greater	13 French	Same as predicate
Packaging:	PETG thermoformed tray Nylon/Tyvek Pouch	Tyvek/Polyester Pouch & Solid Unbleached Sulfate Box and Insert	Same as predicate
Sterilization method:	EtO sterilization	EtO sterilization	Same as predicate
Single-use:	Yes	Yes	Same as predicate
Shelf Life:	6 months	1 year	Same as predicate
Compatible with previously cleared ultrasound systems:	N/A - no previous cleared device It is compatible with the system in this bundle submission (medical device 2)	Yes	Same as predicate
Clinical Performance Data:	No clinical testing is included in the submission. Determination of substantial equivalence is based on an assessment of non-clinical data.	No clinical testing is included in the submission. Determination of substantial equivalence is based on an assessment of non-clinical data.	Same as predicate

Non-clinical performance data:	- UL 60601-1, Safety Requirements for Medical Equipment
	- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
	- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical
	  - Acoustic Output Indices on Diagnostic Ultrasound Equipment
	  - AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic
	  - Ultrasound
	- Safety and EMC Requirements for Medical
		- UL 60601-1, Safety Requirements for Medical Equipment
		- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
		- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical
		  - Acoustic Output Indices on Diagnostic Ultrasound Equipment
		  - AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic
		  - Ultrasound
			Same as predicate

Medical Device 1	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging Catheter	ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter – # K212959	Comparison
	Equipment o EN/IEC 60601-1 EN/IEC 60601-1-2 - ISO 10993-1, Biocompatibility - ISO 11135, Sterilization of health-care products- Ethylene oxide ISO 11607-1 and ISO 11607-2, Packaging for terminally sterilized medical devices	- Safety and EMC Requirements for Medical Equipment o EN/IEC 60601-1 EN/IEC 60601-1-2 - ISO 10993-1, Biocompatibility - ISO 11135, Sterilization of health-care products- Ethylene oxide ISO 11607-1 and ISO 11607-2, Packaging for terminally sterilized medical devices	
Principles of operation:	The VERAFEYE Imaging Catheter provides functionality to inspect and visualize intracardiac as well as intraluminal structures and patient physiology. The device uses ultrasound as the physical imaging modality, where the transducer is integrated within a catheter and steered intra-luminally to a target structure that will be examined by the user. The catheter is delivered via minimally invasive access and enables anatomical visualization to doctors during intraluminal and intracardiac procedures in real time through a software application.	The ACUSON AcuNav Volume Intracardiac Echocardiography (ICE) Catheter is a 12.5F catheter with 90 cm of usable length and four-way steering that provides real-time three-dimensional ultrasound images of anatomical structures and devices, in addition to conventional real-time two-dimensional images.	Same as predicate
Population:	Adult	Adult and pediatric population	Same as predicate

Intended Use Comparison for VERAFEYE Imaging System: Same as the predicate

Intended Use – VERAFEYE Imaging System

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 devices in the heart of adult patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Intended Use of Predicate Device:

Note: in yellow the parts of the Intended Use of the predicate that are applicable to the indication for use Cardiac. The ones used for the Intended Use of VERAFEYE Imaging System

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to (indicate scale with respect to) measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
The typical examinations performed using the SC2000 Ultrasound System are:
Cardiac Imaging Applications and Analysis
The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), & 3D, MMode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.
The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures. The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
Vascular Imaging Applications and Analysis
The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler
(CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images. The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. Superficial Imaging Applications
The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler

(CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.
Intraoperative Imaging Applications
The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler
(CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.
Transcranial Imaging Applications
The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Table 2: Predicate Device: Medical Device 2: VERAFEYE Imaging System

Medical Device 2	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging System v 1.0	ACUSON SC2000 Diagnostic Ultrasound System, K211726	Comparison
Classification:	Class II	Class II	Same as predicate
Regulation:	21 CFR 892.1560 – IYO	21 CFR 892.1560 – IYO 21 CFR 892.1550- IYN 21 CFR 892.1570 – ITX 21 CFR 892.1200 – OBJ 21 CFR 892.2050- LLZ	Same as predicate
Regulation Name:	IYO - Ultrasonic pulsed echo imaging system.	IYO- Ultrasonic pulsed echo imaging system. LLZ- Medical image management and processing system. *Others*	Same as predicate
Product Code:	IYO	IYO, IYN, ITX, OBJ, LLZ	Same as predicate
Indication for Use-Device:	Cardiac - Intracardiac Echocardiography	Cardiac Others (Fetal, Abdominal, Pediatric, Small Organ, Peripheral vessel, Musculo-skeletal (Conventional),	Same as predicate

Medical Device 2	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging System v 1.0	ACUSON SC2000 Diagnostic Ultrasound System, K211726	Comparison
		Musculo-skeletal (Superficial)	
Operating Frequency:	5.25 MHz	Between 1.7 MHz & 10MHz	Same as predicate
Modes:	2D (B-mode) and 3D	B M PWD (Pulse Wave Doppler) CWD (Continuous Wave Doppler) PW DTI (Doppler Tissue Image) Color Doppler Color Power Doppler (CPD) Combined (BMDC)	Same as predicate
Transducers/catheters:	VERAEYE ICE Catheter VF-VIC-001	ACUSON AcuNav Volume Intracardiac Echocardiography Catheter	Same as predicate
System Features			Same as predicate
Patient Registration Fields:	Yes	yes	Same as predicate
Change/Edit Patient Information Active Exam:	Yes	yes	Same as predicate
Volume ICE Package:	Yes (VERAFEYE ICE Catheter VF-VIC-001)	Yes - Acunav Volume Intracardiac Echocardiography Catheter	Same as predicate
Support for AcuNav Volume ICE Catheter connected by SwiftLink Cable:	Yes, Supports VERAFEYE ICE catheter	yes	Same as predicate
2D ICE Package:	Yes (2D B-mode imaging)	yes	Same as predicate
True Volume Imaging Support, AcuNav Volume ICE Catheter:	Yes: volumetric imaging with VERAFEYE ICE catheter	yes	Same as predicate
Cardiac Measurements and Calculations:	Yes: Length & area	yes	Same as predicate
Edit patient data on active exam:	Yes	yes	Same as predicate
Zoom & Pan:	Yes	yes	Same as predicate
Circle Tool:	Yes	yes	Same as predicate
MS Windows 10 OS:	Yes	Windows 10 plus updates	Same as predicate

Medical Device 2	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging System v 1.0	ACUSON SC2000 Diagnostic Ultrasound System, K211726	Comparison
Cybersecurity Features:	Yes	yes	Same as predicate
Security – User Accounts User Accounts \\\local user Authentication:	Yes	yes	Same as predicate
Table side Remote Control:	The VERAFEYE ultrasound imaging system will provide control options through mouse and keyboard	Yes, Joy-stick	Same as predicate
Service Save logs:	Yes	yes	Same as predicate
Security Hot-fix Installation:	Yes: Through USB drive	install a hotfix update via RUH (remote update handling) or USB drive	Same as predicate
Study Back-up and Restore:	Yes	yes	Same as predicate
Monitor:	Yes	Yes	Same as predicate
Output Display Standard (Track 3):	Yes	Yes	Same as predicate
Patient Contact Materials:	Yes	Tested to ISO 10993-1	Same as predicate
UL 60601-1 Certified: *AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)* • *IEC 60601-1-2: 2007(Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests* • *IEC 60601-2-37:2007+A1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment* • *IEC 60601-2-18:2009, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment*	Yes	Yes	Same as predicate

Medical Device 2	Luma Vision Subject Device:	Predicate Device:	
	VERAFEYE Imaging System v 1.0	ACUSON SC2000 Diagnostic Ultrasound System, K211726	Comparison
Additional non-clinical performance data *IEC 62304:2006* *IEC 62366:2014* *AIUM/NEMA UD-3:2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* *• AIUM/NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* *IEC 62359:2010, Ultrasonics – Field characterization – Test Methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*	yes	yes	Same as predicate
Motor Unit:	Motor Unit – VERAFEYE system	**REFERENCE DEVICE** – Motor unit – Ultra ICE Plus - PI 9 MHz Peripheral Imaging Catheter (K181042)	
	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.*	Function: Rotates the inner part of the catheter The reference device is the Motor unit of Ultra ICE catheter (K181042)	Same as reference device

Conclusion:

The VERAFEYE Imaging Catheter and the VERAFEYE Imaging System and predicate devices have identical intended use, principles of operation and technological characteristics.

After analyzing the results of the bench, laboratory and electrical safety tests it can be concluded that the VERAFEYE Imaging Catheter and the predicate device (K212959) are substantially equivalent. After analyzing the results of the bench, laboratory and electrical safety tests, it can be

concluded that the VERAFEYE Imaging System and the predicate device (K211726) are substantially equivalent.

The subject devices (VERAFEYE Imaging Catheter and the VERAFEYE Imaging System) 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.