July 24, 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: K261849
Trade/Device Name: VERAFEYE Imaging Catheter (VF-VIC-002)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: June 25, 2026
Received: June 25, 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,

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

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.	K261849

Please provide the device trade name(s).

VERAFEYE Imaging Catheter (VF-VIC-002)

Please provide your Indications for Use below.

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.

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
Special 510(k) section

K261849

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

Special 510(k) Submission for VERAFEYE Imaging Catheter

Device Information:

Trade / Proprietary Name:	VERAFEYE Imaging Catheter (VF-VIC-002)
Common / Usual Name:	VERAFYEYE Imaging Catheter
Device:	Catheter, Ultrasound, Intravascular
Regulation Description:	Diagnostic Intravascular Catheter
Regulation Number:	21 CFR §870.1200
Device Classification:	Class II
Product Code:	OBJ

Panel: Division of Cardiovascular Devices

Predicate & Reference Devices:

Primary Predicate Device: *K242893*

Trade/Device Name: VERAFEYE Imaging catheter (VIC-001)
Regulation Number: 21CFR 870.1200
Regulatory name: Diagnostic Intravascular Catheter
Regulatory Class: II
Product Code: OBJ

Device Description

The VERAFEYE Imaging catheter is an 11F sterile, single use device for use in the evaluation and guidance of cardiac structures and other devices used during intracardiac procedures. It comprises a transducer array that is located at the distal end of the device; automatic rotation of the transducer array within the catheter body enables the acquisition of 360° degree images.

Also incorporated in the tip of the device are electro-magnetic sensors that enable the localization of the tip of the device relative to the anatomy of the patient and a radio-opaque marker.

The 95cm working length of the device facilitates access to the cardiac anatomy via the femoral vein. An articulation mechanism within the catheter and associated actuators on the handle of the device enable to operator to deflect the distal portion of the device up to 90° in opposing directions.

Connection to the associated VERAFEYE Imaging and Guidance System is achieved via 1m proximal tail of the catheter. The length of the tail enables connection to be made outside of the sterile field.

Provided and packaged with the sterile catheter are two needle guides to assist in the expulsion of air from around the transducer. This is achieved in conjunction with deionized water, that is provided separately as an accessory.

The packaging system comprises a PETG tray that supports the catheter and needle guide. The primary sterile barrier is provided by a Tyvek/Nylon pouch which resides in a cardboard shelf box.

Sterility is achieved via exposure to ethylene oxide.

Packaging contents:

- VERAFEYE Imaging Catheter
- Flushing needle guide (2 units)

LUMA Vision provides the following accessories as part of VERAFEYE Imaging Catheter:

- Catheter flushing liquid (deionized water)

Intended Use: Cardiac

Indications for Use:

The VERAFEYE Imaging Catheter is intended for intracardiac 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 and not for treatment delivery during cardiac interventional percutaneous procedures.

Functional and Technological Comparison

Table 1 below provides a functional and technological comparison between the VERAFEYE Imaging Catheter Version 2 and the legally marketed predicate device, VERAFEYE Imaging Catheter Version 1 (K242893).

The primary difference between the predicate and the subject device is the incorporation of an additional electro-magnetic tracking sensor at the tip of the device. The implementation of the additional sensor enables tracking in 6 degrees of freedom.

Additionally, an acoustic marker placed within the device facilitates co-registration the rotational orientation of the transducer with the catheter body, allowing the VERAFEYE Imaging and Guidance System to generate images with localization data.

As shown in Table 1, the subject device has the same intended use, classification, regulation, product code, imaging modality, and principles of operation as the predicate device. The design changes in Version 2 are limited to incremental enhancements and do not alter the fundamental technology or intended use.

The identified differences do not raise new questions of safety or effectiveness. Substantial equivalence is supported by non-clinical performance testing. No clinical testing was required.

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

Manufacturer/ Component	**Predicate Device: VERAFEYE Imaging catheter v1.0. K#** K242893	**Luma Vision Subject Device: VERAFEYE Imaging catheter v2.0.** **K#** K261849	**Discussion of Equivalence & Differences**
Classification	Class II	Class II	Same as predicate
Regulation	21CFR 870.1200	21CFR 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 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.	Same as predicate
Imaging energy	Ultrasound	Ultrasound	Same as predicate
Acoustic Array	64 channel (segmented aperture)	64 channel (segmented aperture)	Same as predicate
Insertable Outer Diameter:	11 French (3.7mm)	11 French (3.7mm)	Same as predicate
Insertable Length:	Total Insertable length: 95cm - Distal Tip: 51mm	Total Insertable length: 95cm - Distal Tip: 51mm	Same as predicate
Patient Contact	Nylon (ML21)	Nylon (ML21)	Same as predicate

Material (Catheter Body):	Pebax 35, Pebax 55 & Pebax 63 Polymethyl Pentene (TPX) Silicone (grade 4035)	Pebax 35, Pebax 55 & Pebax 63 Polymethyl Pentene (TPX) Silicone (grade 4035)	
Minimum Introducer Sheath Requirement:	12 French or greater	12 French or greater	Same as predicate
Packaging:	PETG thermoformed tray Nylon/Tyvek Pouch	PETG thermoformed tray Nylon/Tyvek Pouch	Same as predicate
Sterilization method:	EtO sterilization	EtO sterilization	Same as predicate
Single-use:	Yes	Yes	Same as predicate
Shelf Life	6 months	6 months	Same as predicate
Compatible with previously cleared ultrasound systems:	Compatible with VERAFEYE Imaging System K242893	It is compatible with the system in the bundle submission (MD2)	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 Equipment o EN/IEC 60601-1 EN/IEC 60601-1-2 ISO 10993-1, Biocompatibility - ISO 11135, Sterilization of	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 Equipment o EN/IEC 60601-1 EN/IEC 60601-1-2 ISO 10993-1, Biocompatibility - ISO 11135, Sterilization of	Same as predicate.

	health-care products- Ethylene oxide ISO 11607-1 and ISO 11607-2, Packaging for terminally sterilized medical devices	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	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	Same as predicate

	intraluminal and intracardiac procedures in real time through a software application.	intraluminal and intracardiac procedures in real time through a software application.	
Population	Adult	Adult	Same as predicate

Non-clinical Performance Testing

Non-clinical performance testing to substantiate the effectiveness of the VERAFEYE Imaging catheter 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	Acoustic performance, Imaging distortion, tracking accuracy,	The catheter can generate the acoustic & electrical signals necessary for the creation of images of cardiac structures & other devices. Localization of the transducer enables positional registration of the images
Operating environment	Acoustic output, surface temperature, dielectric strength	Optimization of output to operate up to the limit of the applicable standards
Clinical workflow	Radio-opacity, catheter, articulation, maneuverability	Ability to access the pertinent regions of the cardiac anatomy. Visualization of the device under fluoroscopy
Lifetime	Run-time, Shelf life	Ability to provide function for the duration of an electrophysiology procedure. Maintenance of a useful shelf life

Conclusion*:*

The VERAFEYE Imaging Catheter and predicate device has identical intended use, principles of operation and technological characteristics.

The changes with respect to the predicate device relate to an extension of the principles of operation and do not change the technological characteristics.

After analysing the results of the bench, laboratory and electrical safety tests it can be concluded that the VERAFEYE Imaging Catheter VIC-002 and the predicate device (K242893) are substantially equivalent.

The subject device (VERAFEYE Imaging Catheter VIC-002) and predicate device (K242893) are 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 device do not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device.