April 11, 2025

Shenzhen Vivolight Medical Device & Technology Co., Ltd.
Gao Pengyang
RA Manager & Regulatory Affairs Department
Room 511-A, 5th Floor, Block B, Building R2,
High-Tech Industrial Park, No. 020
South Seventh Road Gaoxin Community
Shenzhen, Guangdong 518055
China

Re: K242098
Trade/Device Name: Cornaris Intravascular Imaging System (P80-E); Cornaris Intravascular Imaging System (Mobile-E); LumenCross Imaging Catheter (F2)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, DQO
Dated: March 14, 2025
Received: March 14, 2025

Dear Gao Pengyang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for MARCO CANNELLA -S

Aneesh Deoras
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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.

Submission Number *(if known)*

K242098

Device Name

Cornaris Intravascular Imaging System (P80-E);
Cornaris Intravascular Imaging System (Mobile-E);
LumenCross Imaging Catheter (F2)

Indications for Use *(Describe)*

Cornaris Intravascular Imaging System with Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. LumenCross Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The LumenCross Imaging Catheter (referred to as LumenCross) with the Cornaris Intravascular Imaging System produced by Vivolight, which is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The LumenCross intended for use in vessels 2.0~3.5mm in diameter. The LumenCross is not indicated for use in the left main coronary artery or in a target vessel that has undergone a previous bypass procedure.

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.

510(k) #: K242098

510(k) Summary

Prepared on: 2025-04-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Vivolight Medical Device & Technology Co., Ltd.
Applicant Address	Room 511-A, 5th Floor, Block B, Building R2, High-Tech Industrial Park, No. 020, South Seventh Road Gaoxin Community, Yuehai Street, Nanshan District Shenzhen Guangdong 518055 China
Applicant Contact Telephone	86 755 86961139
Applicant Contact	Mr. Gao Pengyang
Applicant Contact Email	gaopengyang@vivo-light.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Cornaris Intravascular Imaging System (P80-E); Cornaris Intravascular Imaging System (Mobile-E); LumenCross Imaging Catheter (F2)
Common Name	Ultrasonic pulsed echo imaging system
Classification Name	System, Imaging, Optical Coherence Tomography (Oct)
Regulation Number	892.1560，870.1200
Product Code(s)	NQQ, DQO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150878	ILUMIEN OPTIS	NQQ
K141453	DRAGONFLY OPTIS IMAGING CATHETER	DQO
K152120	OPTIS Mobile System	NQQ
K230411	Dragonfly OpStar Imaging Catheter	DQO

Device Description Summary

21 CFR 807.92(a)(4)

Cornaris Intravascular Imaging System are cart-mounted computer and Imaging Enging(or optical engine) placed inside an ergonomically designed mobile cart with the cable underground. There are two models, P80-E is mainly composed of trolley, mouse, keyboard, two dispaly monitors, optical engine, computer. Mobile-E is mainly composed of trolley, mouse, keyboard, one display monitor, monitor bracket, optical engine, computer. The both also includes the catheter connection unit (PIU), which provides the interconnection between the Cornaris Intravascular Imaging System and the LumenCross Imaging Catheter.P80-E and Mobile-E has the same software features.

The imaging catheter contains two main components: the catheter body and imaging core (internal rotating fiber optic). The outer diameter of the distal shaft of the catheter was 2.67 F (0.89 mm, 0.035 in.), and the length of the distal shaft was 280mm. The imaging catheter has a working length of 1350mm. The imaging catheter is compatible with 0.014" (0.356 mm) guidewire, which with a guidewire lumen length of 16 mm, the guidewire enters through tip entrance and exit through the RX port. The hydrophilic coating is applied on the outer surface of distal shaft. The LumenCross Imaging Catheter is a single use device. The LumenCross Imaging Catheter

is sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of two years.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Cornaris Intravascular Imaging System with Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. LumenCross Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The LumenCross Imaging Catheter (referred to as LumenCross) with the Cornaris Intravascular Imaging System produced by Vivolight, which is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The LumenCross intended for use in vessels 2.0~3.5mm in diameter. The LumenCross is not indicated for use in the left main coronary artery or in a target vessel that has undergone a previous bypass procedure.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication of Cornaris fall within the indications of the predicate device. The Predicate device has the FFR function, lack of this function have no impact on Imaging function of OCT equipment and does not raise a new intended use.
LumenCross has the same intended use with the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Cornaris is same to the ILUMIEN OPTIS in the following ways:
• Same Mode of Operation for Imaging;
• Same System components;
• Same Optical Parameters for Imaging;
• Same Image Display;
• Same Software Features for Imaging.
and also have the different Characteristics in the following ways:
• Different Dimensions and Weight
• Different Visible Laser Parameters
• Different Pullback length and speed

LumenCross Imaging Catheter is same to the DRAGONFLY OPTIS IMAGING CATHETER in the following ways:
• Same Outer Diameter
• Same Working length
• Same Compatible guide catheter
• Same Compaitible Guidewire
• Same number of Radiopaque marker
• Same Purge
• Same Sterile and single use

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Performance testing was conducted against known standards or the product specification and evaluated the following:

Cornaris Intravascular Imaging System
• Scan range
• Axial resolution
• Luminous Sensitivity
• A-line speed
• Dynamic range
• Frame rate
• Pullback time and range
• Fiber Optic Rotary Joint (FORJ) Insertion loss
• Fiber Optic Rotary Joint (FORJ) Rotational homogeneity
• Fiber Optic Rotary Joint (FORJ) Return loss.

LumenCross Imaging Catheter
• Visual & Dimensional Inspection
• Catheter bond Strength
• Simulated use

• Leakage
• Corrosion
• Torque
• Particulates
• Coating intergrity
• Flexibility and Kink
• Endotoxin

Biological Safety Testing
The LumenCross was subjected to a series of biocompatibility tests in accordance with FDA guidance, using International Standard ISO 10993-1.
• Cytotoxicity
• Sensitization
• Mouse Lymphoma Assay
• Bacterial Reverse Mutation Assay
• Intracutaneous Reactivity
• Acute Systemic Toxicity
• Material Mediated Pyrogenicity
• Hemolysis (Direct and Indirect)
• Complement SC5b-9
• In Vivo Thrombogenicity

Pre-clinical testing
Animal study was conducted to support substantial equivalence. The criteria included Clear Image Length (CIL), Device Performance (system stability, ease of operation, usability of the sterile cover and PIU, catheter crossability, catheter vulnerability, catheter marker visualization), in vivo thrombus formation, and safety. The results demonstrated no significant differences between the subject device and the predicate device.

No clinical study is included in this submission.

The nonclinical tests and pre-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.