March 20, 2025

SpectraWAVE, Inc.
Ankit Shah
Senior Manager Regulatory Affairs
12 Oak Park Dr.
Bedford, Massachusetts 01730

Re: K243016
Trade/Device Name: Starlight Imaging Catheter
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, ORD, OGZ, IYO
Dated: February 18, 2025
Received: February 18, 2025

Dear Ankit Shah:

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
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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)*
K243016

Device Name
Starlight Imaging Catheter

Indications for Use *(Describe)*
Starlight Imaging Catheter with HyperVue Imaging System is intended for imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

The Starlight Imaging Catheter is intended for use in vessels 2.0 to 5.2 mm in diameter.

The Starlight Imaging Catheter is not intended for use in a target vessel which 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) Summary

1. Basic Information-Submitter:

510(k) Owner:	SpectraWAVE, Inc.
Address:	12 Oak Park Drive Bedford, MA 01730 (323) 401-6480
Official Contact:	Ankit Shah Senior Manager Regulatory Affairs (323) 401-6480 ashah@spectrawave.com
Date Summary Prepared:	26 September 2024

2. Device Name:

Trade Name:	Starlight Imaging Catheter
Common Name:	Optical Coherence Tomography Imaging Catheter
Classification Name:	Ultrasonic pulsed echo imaging system
Regulation Numbers:	21 CFR 892.1560
Product Code:	NQQ, ORD, OGZ, IYO
Classification:	Class II

3. Predicate Devices:

- K221257 SpectraWAVE Imaging System

4. Device Description:

The Starlight Imaging Catheter is a sterile, single-use, non-pyrogenic device and consists of two main assemblies: the catheter body and the internal rotating fiber optic imaging core. The catheter has an insertable length of 141 cm and a 2.5 Fr imaging window. It is a rapid exchange design with monorail tip, designed for compatibility with 0.014” (0.355mm) steerable guidewires used during coronary interventional procedures.

The Starlight Imaging Catheter connects to the HyperVue Imaging System through the HyperVue Controller (Controller), a reusable catheter connection allowing

direct control of basic data acquisition. All fiber optic rotation and translational pullback is driven by the Controller and occurs inside the catheter.

5. Indications for Use Statement:

Starlight Imaging Catheter with HyperVue Imaging System is intended for imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

The Starlight Imaging Catheter is intended for use in vessels 2.0 to 5.2 mm in diameter.

The Starlight Imaging Catheter is not intended for use in a target vessel which has undergone a previous bypass procedure.

6. Technological Characteristics:

The subject Starlight Imaging Catheter has same intended use, indications for use, functionality, and operating principle as the previously cleared predicate device. Both the subject and the predicate devices are based on the following same technological elements:

- Used with HyperVue Imaging System for viewing the coronary artery
- Inserted into an artery under fluoroscopic guidance.
- Distal tip delivers near infrared light onto the tissue and collects reflections
- Imaging core moves longitudinally inside a sheath within the vessel to obtain images across the length of the target vessel (pullback).
- Imaging core rotates inside a sheath within the vessel to obtain full 360 degrees to deliver light to create a cross-sectional image.
- Patient population and user remain the same

The following technological differences exist between the subject and predicate devices:

- Different materials on the monorail and optical window
- Different outer and inner diameter on the shaft

These differences do not introduce a new worst case and do not impact safety and effectiveness of the device.

7. Performance Testing:

7.1 Summary of Performance Testing:

Confirmatory testing was performed to verify and validate the design of the subject Starlight Imaging Catheter. This testing was in accordance with the standards and well-established methods used for the predicate devices.

7.2 Sterilization and Shelf Life:

The modifications made to the subject Starlight Imaging Catheter do not impact the Sterilization and Shelf Life of the device.

7.3 Biocompatibility:

The subject device underwent biocompatibility testing in accordance International Standard ISO 10993-1 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The studies performed on the catheter were determined to support the biocompatibility of the device for use in its intended application. The following tests were conducted:

Cytotoxicity
Sensitization
Irritation
Acute Systemic Toxicity
Material Mediated Pyrogenicity
Hemolysis
Hemocompatibility Partial Thromboplastin Time
Hemocompatibility Platelet & Leukocyte
Hemocompatibility Complement Activation
40x Surface Morphology comparison

7.6 Bench testing:

Confirmatory bench tests were performed to demonstrate the modifications do not introduce new concerns of safety and effectiveness. The following tests were done using well-established methods used for the predicate devices:

Optical performance
Catheter deliverability
Pullback performance
Trackability
Kink resistance
Tensile strength

7.7 Animal Testing:

Confirmatory animal study was completed using the well-established methods used for the predicate devices. The animal study demonstrated equivalent performance for the subject device in 3 porcine models that underwent 18 imaging

passes to evaluate for any vascular injury, thrombogenicity, device safety and device performance.

7.8 Summative Usability Testing:

Usability evaluation testing is not required for the modifications being made within this special 510(k).

7.9 Clinical Testing:

No clinical testing is provided in this pre-market notification.

8. Conclusion and Statement of Equivalence:

The information presented in this 510(k) submission demonstrates that the Starlight Imaging Catheter is as safe and effective as the predicate device and is therefore considered substantially equivalent to the predicate device.