June 7, 2023

SpectraWAVE, Inc.
Farzad Parsaie
VP, Quality Assurance & Regulatory Affairs
12 Oak Park Drive
Bedford, Massachusetts 01730

Re: K230691
Trade/Device Name: HyperVue™ Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ, ORD, OGZ, IYO
Dated: March 13, 2023
Received: March 13, 2023

Dear Farzad Parsaie:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230691

Device Name

HyperVue™ Imaging System

Indications for Use *(Describe)*

The HyperVue™ Imaging System is intended for the 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.

The NIRS capability of the HyperVue Imaging System is intended for the detection of lipid core containing plaques of interest.

The NIRS capability of the HyperVue Imaging System is intended for the assessment of coronary artery lipid core burden.

The NIRS capability of the HyperVue Imaging System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

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.

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Traditional 510(k) Summary

1. Submitter Name & Address:

510(k) Owner:	SpectraWAVE, Inc.
Address:	12 Oak Park Drive Bedford, MA 01730 (781) 701-8148
Official Contact:	Farzad Parsaie VP, Quality Assurance & Regulatory Affairs (781) 701-8148 fparsaie@spectrawave.com
Date Prepared:	6/5/2023

2. Device Name:

Trade Name:	HyperVue™ Imaging System
Model Number:	System: 931
Common Name:	Optical Coherence Tomography Imaging System
Classification Name:	System, Imaging, Optical Coherence Tomography Diagnostic intravascular catheter
Regulation Numbers:	21 CFR 892.1560, 21 CFR 870.1200
Product Code:	NQQ, ORD, OGZ, IYO
Classification:	Class II

3. Predicate Device:

- K221257, SpectraWAVE Imaging System and Catheter

4. Device Description:

The HyperVue™ Imaging System is an intravascular imaging device with the ability to simultaneously assess vessel composition and structure by combining Optical Coherence Tomography (OCT) and Near Infrared Spectroscopy (NIRS) in a single catheter-based system.

The HyperVue™ Imaging System consists of the following components:

- **Console:** A mobile platform containing the optical and computing engine, physician and technologist touch displays, power distribution system, and input/output interface.
- **Software:** A proprietary application software that orchestrates the control, acquisition, processing, and display of the OCT-NIRS data.
- **Catheter Interface Unit (CIU):** A tethered CIU that controls the motion of the fiber optic imaging core within the Catheter sheath and connects the Catheter to the Console.
- **Imaging Catheter:** A sterile, single patient use 2.5 French dual-modality imaging catheter containing a rotating fiber optic imaging core inside a protective sterile sheath.

5. Indications for Use Statement:

The HyperVue™ Imaging System is intended for the 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.

The NIRS capability of the HyperVue Imaging System is intended for the detection of lipid core containing plaques of interest.

The NIRS capability of the HyperVue Imaging System is intended for the assessment of coronary artery lipid core burden.

The NIRS capability of the HyperVue Imaging System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

6. Technological Characteristics:

Three of the four system components in the HyperVue™ Imaging System – Console, CIU and Imaging Catheter – are the same as the predicate device. The subject of this application is for the Software module which contains updates with similar technological characteristics and substantially equivalent performance to the cited predicate. **Table 1** below provides a comparative summary (predicate vs proposed device) for the relevant system characteristics/features.

Predicate Device Comparison			
Manufacturer & Model	**PREDICATE DEVICE** **SpectraWAVE, Inc.** **SpectraWAVE Imaging System (K221257)**	**PROPOSED DEVICE** **SpectraWAVE, Inc.** **HyperVue™ Imaging System**	**Discussion of Equivalence & Differences**
Product Code	NQQ – System, imaging, optical coherence tomography ORD – Optical Coherence Tomography, Intravascular Catheter OGZ – Catheter, Intravascular, Plaque Morphology Evaluation IYO – System, Imaging, Pulsed Echo, Ultrasonic	NQQ – System, imaging, optical coherence tomography ORD – Optical Coherence Tomography, Intravascular Catheter OGZ – Catheter, Intravascular, Plaque Morphology Evaluation IYO – System, Imaging, Pulsed Echo, Ultrasonic	Same
Intended Use	The SpectraWAVE Imaging System and the SpectraWAVE Imaging Catheter are intended for the imaging of coronary arteries.	The HyperVue™ Imaging System and the Starlight™ Imaging Catheter are intended for the imaging of coronary arteries.	Same Added tradenames only
Intended Users	Physicians and healthcare professionals	Physicians and healthcare professionals	Same
Operational Environment	Cardiac catheterization laboratory	Cardiac catheterization laboratory	Same
Indications For Use	The SpectraWAVE Imaging System is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The SpectraWAVE Imaging Catheter is intended for use in vessels 2.0 to 5.2 mm in diameter. The SpectraWAVE Imaging Catheter is not intended for use in a target vessel which has undergone a previous bypass procedure.	The HyperVue™ Imaging System is intended for the 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. The NIRS capability of the HyperVue Imaging System is intended for the detection of lipid core containing plaques of interest.	Same Added tradenames only

Predicate Device Comparison			
Manufacturer & Model	**PREDICATE DEVICE** **SpectraWAVE, Inc.** **SpectraWAVE Imaging System (K221257)**	**PROPOSED DEVICE** **SpectraWAVE, Inc.** **HyperVue™ Imaging System**	**Discussion of Equivalence & Differences**
	The NIRS capability of the SpectraWAVE Imaging System is intended for the detection of lipid core containing plaques of interest. The NIRS capability of the SpectraWAVE Imaging System is intended for the assessment of coronary artery lipid core burden. The NIRS capability of the SpectraWAVE Imaging System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.	The NIRS capability of the HyperVue Imaging System is intended for the assessment of coronary artery lipid core burden. The NIRS capability of the HyperVue Imaging System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.	
Primary Functions	Delivers energy (infrared light) to the tissue. Measures the depth and pattern of reflections from the tissue from the return near-infrared light to create high-resolution, real-time images. Stores images for evaluation and review.	Delivers energy (infrared light) to the tissue. Measures the depth and pattern of reflections from the tissue from the return near-infrared light to create high-resolution, real-time images. Stores images for evaluation and review.	Same
Image Creation, Display and Storage	Process reflected optical signals to construct images. Display images. Store images.	Process reflected optical signals to construct images. Display images. Store images.	Same
Measure Vessel Cross Sectional Area	Calculate and report vessel cross-sectional area	Calculate and report vessel cross-sectional area	Same
Measure Vessel Linear Dimensions	Calculate and display vessel diameter at user specified locations within the displayed image	Calculate and display vessel diameter at user specified locations within the displayed image	Same

Predicate Device Comparison			
Manufacturer & Model	**PREDICATE DEVICE** **SpectraWAVE, Inc.** **SpectraWAVE Imaging System (K221257)**	**PROPOSED DEVICE** **SpectraWAVE, Inc.** **HyperVue™ Imaging System**	**Discussion of Equivalence & Differences**
Calculate Vessel Physical Parameters	Calculate and display mathematical comparisons of image data such as % reduction from average, length of narrowing.	Calculate and display mathematical comparisons of image data such as % reduction from average, length of narrowing.	Same
Procedural Steps	System set-up, patient data entry, catheter preparation insertion of catheter into the artery under fluoroscopic guidance, proper positioning of the catheter distal to the target vessel, image acquisition, and evaluation of the acquired images.	System set-up, patient data entry, catheter preparation insertion of catheter into the artery under fluoroscopic guidance, proper positioning of the catheter distal to the target vessel, image acquisition, and evaluation of the acquired images.	Same
Use of Results	Physicians evaluate the images in combination with other tests and evaluations to assess the patient's coronary arteries.	Physicians evaluate the images in combination with other tests and evaluations to assess the patient's coronary arteries.	Same
Operating System (OS)	Windows-based (Windows Professional Desktop)	Windows-based (Windows Enterprise IoT) • Windows Enterprise IoT OS provides configurability for deploying a single-purpose dedicated system.	Substantially equivalent There is no difference in the fundamental performance and intended use of the software due to change to OS
User Convenience Features	Computer-aided measurement tools, such as border contours, computation of cross-sectional area, and percent stenosis. Display of live angiography imagery on the SpectraWAVE Imaging System display monitors.	Computer-aided measurement tools, such as border contours, computation of cross-sectional area, and percent stenosis. Display of live angiography imagery on the HyperVue™ Imaging System display monitors.	Substantially equivalent The additional features are minor changes compared to the predicate and were added to the

Predicate Device Comparison			
Manufacturer & Model	**PREDICATE DEVICE** **SpectraWAVE, Inc.** **SpectraWAVE Imaging System (K221257)**	**PROPOSED DEVICE** **SpectraWAVE, Inc.** **HyperVue™ Imaging System**	**Discussion of Equivalence & Differences**
		The following updates have been added compared to the predicate device: • Addition of new user-selectable and optional image overlays on the displayed viewports (Angiography & OCT-NIRS) to highlight OCT/NIRS-derived features. • Update to User Interface (UI) look-and-feel and clinical workflow	proposed device to provide user-selectable and optional user convenience features. No changes were made to the intended use or indications of use of the device.

7. Performance Testing:

7.1 Summary of Performance Testing:

Design verification and validation (V&V) of the HyperVue™ Imaging System with the updated software were performed in compliance with external standards and internal design control procedures. V&V testing comprised of system/software verification and summative usability testing to confirm device performance.

7.2 Sterilization and Shelf Life:

No change from K221257. Sterilization and shelf life are not impacted since this 510(k) submission covers only a software update for the HyperVue™ Imaging System.

7.3 Biocompatibility:

No change from K221257. Biocompatibility is not impacted since this 510(k) submission covers only a software update for the HyperVue™ Imaging System.

7.4 Software:

HyperVue™ Imaging System and Application Software were developed and tested in compliance with IEC 62304. Software verification and validation were conducted to FDA regulations, standards, and guidance document requirements. The results of this testing conclude the software has met these requirements.

7.5 EMC/Basic Electrical Safety:

No change from K221257. This 510(k) submission covers only a software update package for the HyperVue™ Imaging System. EMC & Basic Electrical Safety are not impacted by this software update.

7.6 Bench testing:

In addition to the software verification testing described above, benchtop testing of the entire device was conducted to evaluate certain system-level features, such as measurements, that require both hardware and software to evaluate. The results of this testing conclude the system has met these requirements.

7.7 Animal Testing:

Not applicable. No animal testing was necessary to demonstrate equivalence.

7.8 Human Factors Engineering (HFE) Usability Study:

Usability evaluation was conducted to establish that the updated software for the HyperVue™ Imaging System meets the needs of the intended users to perform OCT-NIRS imaging safely and effectively according to ANSI/AAMI/IEC 62366-1.

The updated software for the HyperVue™ Imaging System has been found to be safe and effective for the intended users, uses, and use environments.

7.9 Clinical Testing:

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

8. Conclusion and Statement of Equivalence:

Modifications to the software of the device presented in this 510(k) submission do not raise new questions of safety or effectiveness. As demonstrated by risk management activities, software verification, and HFE usability study testing, the proposed HyperVue™ Imaging System does not raise new questions of safety or effectiveness and is therefore considered substantially equivalent to the predicate device.