July 16, 2025

SpectraWAVE, Inc.
Ankit Shah
Sr. Manager Regulatory Affairs
12 Oak Park Drive
Bedford, Massachusetts 01730

Re: K251198
Trade/Device Name: HyperVue™ Software
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: April 17, 2025
Received: April 17, 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
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.	K251198

Please provide the device trade name(s).

HyperVue™ Software

Please provide your Indications for Use below.

The HyperVue Software is intended to be used only with compatible HyperVue Imaging Systems and Starlight Imaging Catheter.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter Name & Address:

510(k) Owner:	SpectraWAVE, Inc.
Address:	12 Oak Park Drive Bedford, MA 01730 (781) 701-8148
Official Contact:	Ankit K. Shah Senior Manager Regulatory Affairs (323) 401 6480 ashah@spectrawave.com
Date Prepared:	4/15/2025
510(k) Number:	K251198

2. Device Name:

Trade Name	HyperVue™ Software
Common Name	Optical Coherence Tomography Imaging System
Classification Name	System, Imaging, Optical Coherence Tomography
Regulation Number	21 CFR 892.1560
Product Code	NQQ
Classification	Class II

3. Predicate Device:

- Predicate Device: K230691, HyperVue Imaging System
- Recall Status: The predicate device (K230691) has not been subject to a design-related recall.

4. Device Description:

The HyperVue Software (2.0) is resident on the HyperVue Imaging System (K230691) and is used with the Starlight Imaging Catheter (K243016). The HyperVue Software provides a user interface for executing clinical workflows, acquiring and processing

OCT-NIRS data, and exporting patient data. The software update introduces the ability to connect to hospital PACS servers for data export.

Indications for Use Statement:

The HyperVue Software is intended to be used only with compatible HyperVue Imaging Systems and Starlight Imaging Catheter.

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

5. Technological Characteristics:

The HyperVue Software has same intended use, indications for use, functionality, and operating principle as the predicate device. Differences, such as the ability to connect to PACS servers and historical software and algorithm changes do not raise new questions of safety and effectiveness.

	PREDICATE DEVICE **SpectraWAVE, Inc.** **HyperVue Imaging System (K230691)**	**SUBJECT DEVICE** **SpectraWAVE, Inc.** **HyperVue™ Software (2.0)**	**Comparison**
Product Code	Classification Product Code: NQQ, Subsequent Product Code: ORD, OGZ, IYO	Classification Product Code: NQQ	Same Classification Product Code
Intended Use	The HyperVue™ Imaging System and the SpectraWAVE Starlight™ Imaging Catheter are intended for the imaging of	The HyperVue™ Imaging System Software is used withing the HyperVue Imaging System which is used with the Starlight™ Imaging Catheter	Same

	PREDICATE DEVICE SpectraWAVE, Inc. HyperVue Imaging System (K230691)	SUBJECT DEVICE SpectraWAVE, Inc. HyperVue™ Software (2.0)	Comparison
	coronary arteries.	intended for the imaging of coronary arteries.	
Intended Users	Physicians and healthcare professionals	Physicians and healthcare professionals	Same
Operational Environment	Cardiac catheterization laboratory	Cardiac catheterization laboratory	Same
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.	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.	Different The difference compared to the predicate device includes extending the export feature to allow transferring DICOM format data to network connected hospital PACS servers
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
Calculate Vessel Physical Parameters	Calculate and display mathematical comparisons of image data such as % reduction from average, length of narrowing, cross-sectional area.	Calculate and display mathematical comparisons of image data such as % reduction from average, length of narrowing, cross-sectional area.	Same
Use of Results	Physicians evaluate the images in combination with other tests and evaluations to	Physicians evaluate the images in combination with other tests and evaluations to	Same

	PREDICATE DEVICE SpectraWAVE, Inc. HyperVue Imaging System (K230691)	SUBJECT DEVICE SpectraWAVE, Inc. HyperVue™ Software (2.0)	Comparison
	assess the patient's coronary arteries.	assess the patient's coronary arteries.	
Operating System (OS)	Windows-based (Windows Enterprise IoT)	Windows-based (Windows Enterprise IoT)	Same
User Convenience Features	Computer-aided measurement tools, such as border contours, computation of cross-sectional area, user-selectable image overlays, and percent stenosis. Display of live angiography imagery on the HyperVue Imaging System display monitors.	Computer-aided measurement tools, such as border contours, computation of cross-sectional area, user-selectable image overlays, and percent stenosis. Display of live angiography imagery on the HyperVue Imaging System display monitors.	Different **New Features added include: Export feature allowing transferring DICOM format data to network connected hospital PACS servers**

6. Performance Data:

6.1 Non-Clinical Testing:

HyperVue software was tested in accordance with an established test plan that fully evaluated all functions performed by the software. Design verification documents were developed to provide evidence for unit, integration, system level, regression, information security, and validation software tests. In addition to the software verification, cybersecurity testing including Static Code Analysis, Vulnerability Scanning, Penetration Testing, verification of Security Controls, and interoperability assessment was performed as per FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". Additionally, User Requirement, Design Requirement, and Cybersecurity test reports were developed. The HyperVue software passed all pre-determined acceptance criteria identified in the test plan.

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "*Guidance on Software Contained in Medical Devices*". Potential security and safety related risk which includes unauthorized system access and misuse of patient data arising from the new or updated features were analyzed and satisfactorily mitigated by implementing and testing robust cybersecurity

controls consistent with the SpectraWAVE's SPDF and the Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. threat model. Instructions for Cybersecurity and Account Settings were included in the device labeling for the HyperVue Software.

HyperVue is substantially equivalent in design concepts, technologies and operating principle to the identified predicate. This version of the HyperVue software does not present any new questions of safety or effectiveness.

7. Conclusion and Statement of Equivalence:

The information presented in this 510(k) submission demonstrates that the HyperVue Software is as safe and as effective, and performs as well as or better than the predicate device, and is therefore considered substantially equivalent to the predicate device.