



October 17, 2025

SpectraWAVE, Inc.  
% Ankit Shah  
Senior Manager Regulatory Affairs  
12 Oak Park Drive  
BEDFORD, MA 01730

Re: K251355  
Trade/Device Name: X1-FFR  
Regulation Number: 21 CFR 892.1600  
Regulation Name: Angiographic X-Ray System  
Regulatory Class: Class II  
Product Code: QHA, LLZ  
Dated: September 15, 2025  
Received: September 16, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue watermark of the FDA logo is visible in the background. Overlaid on this watermark is a handwritten signature in black ink that reads "Lu Jiang".

Lu Jiang, Ph.D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiologic Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251355

Device Name

X1-FFR

Indications for Use (Describe)

The SpectraWAVE X1-FFR Software features segmentation of coronary vessels, and measurement and reporting tools to facilitate the following use:

- Calculate the dimensions of coronary vessels;
- Quantify stenosis in coronary vessels;
- Quantify pressure drop in coronary vessels;

The SpectraWAVE X1-FFR Software is intended to be used by or under the supervision of a cardiologist.

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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## 510(k) Summary

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### Traditional 510(k) Summary

#### 1. Basic Information-Submitter:

510(k) Owner: SpectraWAVE, Inc.

Address: 12 Oak Park Drive  
Bedford, MA 01730  
(781) 701-8148 (main number)

Official Contact: Ankit Shah  
Senior Manager, Regulatory Affairs  
(323) 401-6480  
[ashah@spectrawave.com](mailto:ashah@spectrawave.com)

Date Summary Prepared: 10/17/2025

#### 2. Device Name:

Trade Name: X1-FFR

Common Name: X-Ray Angiographic Imaging Based Coronary  
Vascular Simulation Software Device

Classification Name: Angiographic x-ray system

Regulation Numbers: 21 CFR 892.1600

Product Code: QHA, LLZ

Classification: Class II

#### 3. Predicate Devices:

K180019 Pie Medical Imaging CAAS Workstation

#### 4. Device Description:

The SpectraWAVE X1-FFR Software is a standalone medical device which is used in the catheterization lab as an angiography image assessment tool for assessing Fractional Flow Reserve using non-invasive quantitative and functional analysis of coronary vasculature.

The SpectraWAVE X1-FFR software comprises image processing and computational algorithms to perform functional coronary angiography, providing longitudinal estimations of coronary pressure drop and Fractional Flow Reserve (FFR) during angiogram and percutaneous coronary intervention (PCI) procedures.

The SpectraWAVE X1-FFR Software is a procedural aid intended to be used to support diagnosis by clinicians.

AI-derived algorithms are deployed on the device to support vessel segmentation and contouring. Analytical (non-AI) models are used for generating FFR values.

The SpectraWAVE X1-FFR Software

- provides measurements of localized coronary pressure drops over the length of a coronary vessel, including the right and left coronary tree.
- provides dimensions of the coronary vessels and the amount of stenosis in coronary vessels;
- enables physiology assessment in a non-invasive manner, without the need for adenosine and without the need for additional radiation and contrast administration.

#### **5. Indications for Use Statement:**

The SpectraWAVE X1-FFR Software features segmentation of coronary vessels, and measurement and reporting tools to facilitate the following use:

- Calculate the dimensions of coronary vessels;
- Quantify stenosis in coronary vessels;
- Quantify pressure drop in coronary vessels;

The SpectraWAVE X1-FFR Software is intended to be used by or under the supervision of a cardiologist.

#### **6. Comparison of Technological Characteristics:**

A comparison of the technological characteristics of the subject and the predicate device is provided in the table below.

	<b>SUBJECT DEVICE</b>	<b>PREDICATE DEVICE</b>	<b>Comparison</b>
	<b>SpectraWAVE X1-FFR</b>	<b>Pie Medical CAAS Workstation (K180019)</b>	
<b>Company</b>	SpectraWAVE 12 Oak Park Drive Bedford, MA 01730, USA	Pie Medical Imaging BV Philipsweg 1, 6227 AJ Maastricht, The Netherlands	
<b>Intended Use</b>	The SpectraWAVE X1-FFR Software is a software product intended to be used by or under the supervision of a cardiologist in order to aid in reading, co-registering, and interpreting cardiovascular X-ray images to support in diagnoses and for assistance during the intervention of cardiovascular conditions.	CAAS Workstation is a modular software product intended to be used by or under supervision of a cardiologist or radiologist in order to aid in reading, co-registering and interpreting cardiovascular X-Ray images to support diagnoses and for assistance during intervention of cardiovascular conditions.	Identical
<b>Indications for Use</b>	<p>The SpectraWAVE X1-FFR Software features segmentation of coronary vessels, and measurement and reporting tools to facilitate the following use:</p> <ul style="list-style-type: none"> <li>• Calculate the dimensions of coronary vessels;</li> <li>• Quantify stenosis in coronary vessels;</li> <li>• Quantify pressure drop in coronary vessels;</li> </ul> <p>The SpectraWAVE X1-FFR Software is intended to be used by or under the supervision of a cardiologist.</p>	<p>CAAS Workstation features segmentation of cardiovascular structures, 3D reconstruction of vessel segments and catheter path based on multiple angiographic images, measurement and reporting tools to facilitate the following use:</p> <ul style="list-style-type: none"> <li>• Calculate the dimensions of cardiovascular structures;</li> <li>• Quantify stenosis in coronary and peripheral vessels;</li> <li>• Quantify the motion of the left and right ventricular wall;</li> <li>• Perform density measurements;</li> <li>• Determine C-arm position for optimal imaging of cardiovascular structures;</li> <li>• Enhance stent visualization and measure stent dimensions;</li> </ul>	<p>The subject device indications are identical to a subset of the indications cleared for the predicate device.</p> <p>Indications for the subject device focus on the assessment of coronary vessels.</p>

	<b>SUBJECT DEVICE</b>	<b>PREDICATE DEVICE</b>	<b>Comparison</b>
	<b>SpectraWAVE X1-FFR</b>	<b>Pie Medical CAAS Workstation (K180019)</b>	
		<ul style="list-style-type: none"> <li>Quantify pressure drop in coronary vessels;</li> <li>Co-registration of angiographic X-Ray images with IVUS and OCT images.</li> </ul> <p>CAAS Workstation is intended to be used by or under supervision of a cardiologist or radiologist.</p>	
<b>Regulation Number</b>	21 CFR 892.1600	21 CFR 892.1600	Identical
<b>FDA Product Code</b>	QHA, LLZ	QHA, LLZ	Identical
<b>Data Input</b>	X-ray angiography in Display format (vendor independent)	X-ray angiography in DICOM format (vendor independent); <ul style="list-style-type: none"> <li>IVUS and OCT data in DICOM format (vendor independent);</li> <li>IVUS data as video stream</li> </ul>	<p>The subject device data input type is similar to a subset of the data inputs cleared for the predicate device.</p> <p>The subject device uses X-Ray angiography in display format and does not accept other image types.</p>
<b>Image Display</b>	<ul style="list-style-type: none"> <li>2D X-Ray Image</li> </ul>	<ul style="list-style-type: none"> <li>2D X-ray image;</li> <li>3D reconstruction based on 2 Xray images;</li> <li>2D intravascular image;</li> <li>Longitudinal intravascular reconstruction</li> </ul>	<p>The subject device's image display outputs are identical to a subset of the image display outputs cleared for the predicate device.</p>

	<b>SUBJECT DEVICE</b>	<b>PREDICATE DEVICE</b>	<b>Comparison</b>
	<b>SpectraWAVE X1-FFR</b>	<b>Pie Medical CAAS Workstation (K180019)</b>	
			The subject device displays 2D X-Ray Images and does not display 3D reconstruction or intravascular formats.
<b>Image Assessment</b>	<ul style="list-style-type: none"> <li>• Automatic calibration;</li> <li>• Vessel dimensions (diameters, lengths);</li> <li>• Automatic and manual stenosis assessment;</li> <li>• Pressure drop calculation in coronary vessel</li> </ul>	<ul style="list-style-type: none"> <li>• Manual and automatic calibration;</li> <li>• Basic length, diameter, density and angle measurements;</li> <li>• Vessels and ventricle dimensions (diameters, areas, volumes);</li> <li>• Automatic and manual stenosis assessment;</li> <li>• Left and right ventricular wall motion;</li> <li>• Left ventricular myocardium dimensions;</li> <li>• Enhanced stent visualization;</li> <li>• Stent dimensions;</li> <li>• Pressure drop calculation in coronary vessels;</li> <li>• Providing common frame of reference for IVUS and OCT data with X-ray angiographic data</li> </ul>	<p>The subject device's image assessment capabilities are identical to a subset of the image assessment capabilities cleared for the predicate device.</p> <p>The subject device's image assessment focuses on the analysis of coronary vessels.</p>

## **7. Performance Testing:**

### **7.1 Summary of Performance Testing:**

Design verification and validation of the SpectraWAVE X1-FFR Software were performed in compliance with external standards and internal design control procedures comprised of software development, bench testing (software and algorithm), and summative usability testing to confirm device performance.

### **7.2 Software:**

SpectraWAVE X1-FFR Software was developed and tested in compliance with IEC 62304. Software verification and validation were conducted in accordance with applicable FDA regulations, standards, and guidance document requirements. The results of this testing conclude the software has met these requirements.

### **7.3 Performance Data:**

SpectraWAVE performed a series of tests to demonstrate that the X1-FFR Software meets its performance specifications. Comprehensive verification and validation activities were successfully completed, raising no safety or effectiveness concerns. All testing passed the acceptance criteria.

X1-FFR performance relative to invasive hyperemic pressure wire was assessed in a retrospective clinical analysis of 306 vessels from 285 patients. The mean age of the patients included in the study was 66 years old, and 73% were male. Of the 306 vessels analyzed, 65% were LAD, 17% were RCA, and 17% were LCX. The average FFR across the population was 0.82. A Bland-Altman analysis assessing the relationship between X1-FFR and invasive hyperemic pressure wire evaluation across the entire dataset demonstrated a bias of 0.00 with 95% limits of agreement of [-0.12, 0.12].

#### **7.4 Cybersecurity**

SpectraWAVE X1-FFR Software's cybersecurity and interoperability risks have been appropriately mitigated to provide reasonable assurance of the safety and effectiveness of the device.

#### **7.5 Summative Usability Testing:**

Usability evaluation was conducted to establish that the SpectraWAVE X1-FFR Software meets the needs of the intended users to perform assessment of blood flow through the coronary artery, safely and effectively according to ANSI/AAMI/IEC 62366-1.

The SpectraWAVE X1-FFR Software has been found to be safe and effective for the intended users, indications for use, and use environments.

#### **8. Conclusion and Statement of Equivalence:**

The information presented in this 510(k) submission demonstrates that the SpectraWAVE X1-FFR Software is as safe and effective as the predicate device and is therefore considered substantially equivalent to the predicate device.