February 28, 2023

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

Re: K221257
Trade/Device Name: SpectraWAVE 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: February 24, 2023
Received: February 24, 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)*
K221257

Device Name

SpectraWAVE Imaging System

Indications for Use *(Describe)*

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 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.

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

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:	Farzad Parsaie VP, Quality Assurance & Regulatory Affairs (781) 701-8148 (main number) fparsaie@spectrawave.com
Date Summary Prepared:	28 February 2023

2. Device Name:

Trade Name:	SpectraWAVE Imaging System
Model Number:	System: 931; Catheter: 951
Common Name:	Optical Coherence Tomography Imaging System
Classification Name:	Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter
Regulation Numbers:	21 CFR 892.1560, 21 CFR 870.1200
Product Code:	NQQ, ORD, OGZ, IYO
Classification:	Class II

3. Predicate Devices:

- K192019 Dragonfly OpStar™ Imaging Catheter, AptiVue™ Software version E.5.1
- K183599 Infraredx, Inc. Makoto Intravascular Imaging System™, Dualpro™ IVUS+NIRS Imaging Catheter- secondary predicate

4. Device Description:

The SpectraWAVE 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 SpectraWAVE 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 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 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.

6. Technological Characteristics:

The SpectraWAVE Imaging System is utilizing a primary and secondary predicate device as the product combines features of two predicate devices with the same intended use into a single new device. As shown in Tables 1 and 2 below, the SpectraWAVE Imaging System is substantially equivalent to the respective features of the two predicate devices because it has the same intended use, and the technological characteristics are similar and substantially equivalent to the cited predicates.

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
510(k) Number	This submission	K192019	NA
Product Code	NQQ – System, imaging, optical coherence tomography ORD – Optical Coherence Tomography, Intravascular Catheter	NQQ – System, imaging, optical coherence tomography DQO – Catheter, Intravascular, Diagnostic	Same for NQQ code Substantially equivalent for ORD vs DQO codes. While the predicates used DQO as an additional code, the ORD code is more exact for both the proposed and predicate devices.
Intended Use	The SpectraWAVE Imaging System and the SpectraWAVE Imaging Catheter are intended for the imaging of coronary arteries.	The OPTIS Imaging System with Dragonfly OpStar Imaging Catheter is intended for the imaging of coronary arteries.	Same
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 Dragonfly OpStar™ imaging catheter with OCT imaging system is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly OpStar Imaging Catheter is intended for use in	Substantially equivalent for the OCT portion of the device. The scan range of the SpectraWAVE

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
	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 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.	vessels 2.0 to 3.5 mm in diameter. The Dragonfly OpStar 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 AptiVue™ E-series software is intended for use only with compatible OPTIS™ imaging systems. The OPTIS imaging system with a compatible Dragonfly™ imaging catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The compatible Dragonfly™ imaging catheters are intended for use in vessels 2.0 to 3.5 mm in diameter. The compatible Dragonfly™ imaging catheters are not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS imaging system is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise	Imaging System allows imaging of vessels up to 5.2mm in diameter, which covers the expected range of left main coronary arteries.

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
		and clinical judgment to determine if therapeutic intervention is indicated.	
System Components	Imaging System reusable electrical mechanical unit Intravascular imaging catheter Disposable accessories	Imaging System reusable electrical mechanical unit Intravascular imaging catheter Disposable accessories	Substantially Equivalent
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
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

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
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 and flushing, 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.	Substantially Equivalent
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
Imaging Catheter			
Primary Functions	To position the catheter into the vessel to be imaged. To deliver near infrared light to tissues. To collect reflections.	To position the catheter into the vessel to be imaged. To deliver near infrared light to tissues. To collect reflections.	Same
Design Features	Rapid exchange, mono-rail tip design with two sub-assemblies (catheter sheath and imaging core).	Rapid exchange, mono-rail tip design with two sub-assemblies (catheter sheath and imaging core).	Same
Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Guide Wire Compatibility	Compatible with 0.014" guide wires	Compatible with 0.014" guide wires	Same
Dimensions, Catheter	2.5 Fr diameter window 141 cm insertable length	$\leq$ 3.0 Fr diameter window 135 cm (min) insertable length	Substantially equivalent. Performance test data, including

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
			bench, in-vitro and in-vivo testing, demonstrates that the images and measurements provided by the SpectraWAVE Imaging System are substantially equivalent to the Abbott OPTIS Imaging System and Dragonfly OpStar Imaging Catheter.
Tip Design	Distal tip delivers near infrared light onto the tissue and collects reflections	Distal tip delivers near infrared light onto the tissue and collects reflections	Same
Body Contact	Direct blood contact	Direct blood contact	Same
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Same
Insertion	Inserted into an artery under fluoroscopic guidance. Catheter positioned distal to the target region in the vessel to be imaged.	Inserted into an artery under fluoroscopic guidance. Catheter positioned distal to the target region in the vessel to be imaged.	Same
Rotational Movement	Imaging core rotates inside a sheath within the vessel to obtain full 360 degrees to deliver light to create a cross-sectional image.	Imaging core rotates inside the sheath within the vessel to obtain full 360 degrees to deliver light to create a cross-sectional image.	Same

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
Longitudinal Movement	Imaging core moves longitudinally inside a sheath within the vessel to obtain images across the length of the target vessel (pullback).	Imaging core moves longitudinally inside a sheath within the vessel to obtain images across the length of the target vessel (pullback).	Same
Reusable Electrical Mechanical Unit			
Energy Source	Near infrared light	Near infrared light	Same
Weight	200 lbs (approximate)	< 209 lbs (approximate)	Substantially equivalent
Operating Conditions	10 - 32°C 5 – 80% RH, non-condensing	10 - 32°C 30 - 80% Relative Humidity	Substantially equivalent
Imaging and Pullback Specifications			
Catheter Rotational Rate	200 per second	180 per second	Substantially equivalent
Frame Rate	200 per second	180 per second	Substantially equivalent
Automated Pullback	Yes	Yes	Same
Image Length	50 mm / 110 mm	54 mm / 75 mm	Substantially equivalent
Image Collection Time	Approximately 2 seconds	Approximately 2-4 seconds	Substantially equivalent

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
Catheter Preparation	No flush	Contrast flush	Substantially equivalent. The OCT predicate requires flushing the catheter with contrast; however, the SpectraWAVE Imaging Catheter does not require a contrast flush.
Minimum Guide Catheter	≥ 6 Fr	≥ 6 Fr	Same
Catheter Configuration	Single optical imaging catheter, mechanically rotated	Single optical imaging element, mechanically rotated	Same
Proximal End Configuration	Single connector, mechanical snap in motor drive unit	Single connector, mechanical snap in motor drive unit	Same
User Interface and Displays			
Sterile Barrier Interface	Catheter Interface Unit encapsulated in single use disposable bag	Motor Drive Unit encapsulated in single use disposable bag	Same
Configuration	Mobile cart with braking system	Mobile cart with braking system	Same
User Input	Touch screen	Keyboard and mouse	Substantially equivalent
Data Storage	Native format	DICOM and native format	Substantially equivalent

Table 1: Primary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**Abbott Medical**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**OPTIS Imaging System** **Dragonfly OpStar™ Imaging Catheter**	
Monitors	Two high resolution touch-screen monitors	Two high resolution monitors	Substantially equivalent
Software Program	Windows-based	Windows-based	Same
Displays	Cross-sectional image (frame) Longitudinal view	Cross-sectional image (frame) Longitudinal view	Same
User Convenience Features	Computer aided measurement tools, such as border contours. Computation of cross-sectional area and percent stenosis.	Image notation. Computer aided measurement tools, such as border contours. Computation of cross-sectional area and percent stenosis.	Substantially equivalent.

Table 2: Secondary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**InfraReDx, Inc.**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**Makoto Intravascular Imaging System™ Dualpro™ IVUS+NIRS Imaging Catheter**	
510(k) Number	This submission	K183599	NA
Product Function	Near Infrared Imaging System	Near Infrared and Ultrasound Imaging System	Substantially equivalent for NIRS portion of the system
Product Code	OGZ – Catheter IYO – System	OGZ – Catheter IYO – System	Substantially equivalent The SpectraWAVE Imaging System is a combined system. See primary predicate.
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 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	1. The Makoto Intravascular Imaging System™ is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography. a. The System is intended for the detection of lipid-core-containing plaques of interest. b. The System is intended for the assessment of coronary artery lipid core burden. c. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events. 2. The System is intended for ultrasound examination of coronary intravascular pathology. a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	Substantially equivalent to the NIRS portion of the SprectraWAVE Imaging System.

Table 2: Secondary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**InfraReDx, Inc.**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**Makoto Intravascular Imaging System™ Dualpro™ IVUS+NIRS Imaging Catheter**	
	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.		
System Components	NIR Catheter Portable Console (Laser, computer, power supply) and Controller	NIR/IVUS Catheter Portable or Fixed Console (Laser, SBC, power supply) and Controller	Substantially equivalent
Imaging Mode	Near Infrared Light	Near Infrared light, Ultrasound	Substantially equivalent to the NIRS portion of predicate
Output	NIR Light	NIR light RF Ultrasound	Substantially equivalent to the NIRS portion of predicate
Laser Type	Swept source semiconductor laser	Swept source semiconductor laser	Same
Image Element Pullback Speed	60 mm/s	0.5, 1.0, and 2.0 mm/s	Substantially equivalent. Ability of system to perform pullback and acquire data at specified speed is demonstrated through system verification. With respect to post-processing, NIRS Verification &

Table 2: Secondary Predicate Device Comparison			
Manufacturer	**SpectraWAVE, Inc.**	**InfraReDx, Inc.**	**Discussion of Equivalence & Differences**
Model	**SpectraWAVE Imaging System**	**Makoto Intravascular Imaging System™ Dualpro™ IVUS+NIRS Imaging Catheter**	
			Validation summarizes the NIRS performance of the SpectraWAVE system, with the predicate device as a reference.

7. Performance Testing:

7.1 Summary of Performance Testing:

Design verification and validation of the SpectraWAVE Imaging System were performed in compliance with external standards and internal design control procedures comprised of Sterilization and shelf life, Biocompatibility, Software, EMC/Electrical Safety, bench testing, animal testing, and summative usability testing to confirm device performance.

7.2 Sterilization and Shelf Life:

Sterilization validation was performed to ensure a SAL of 10^{-6}, according to international sterilization standards.

Visual Inspection, Leak, and Seal Strength testing were used to evaluate the integrity of the packaging configuration. Testing was conducted after sterilization, environmental conditioning including aging, and simulated shipping and distribution.

7.3 Biocompatibility:

The SpectraWAVE Imaging Catheter was subjected to a series of biocompatibility tests in accordance with FDA guidance, using International Standard ISO 10993-1. The studies performed on the SpectraWAVE Imaging Catheter were determined to support the biocompatibility of the device for use in its intended application.

7.4 Software:

SpectraWAVE 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:

The SpectraWAVE Imaging System has been tested and is in compliance with general safety requirements, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62366-1, and IEC 60825-1.

7.6 Bench testing:

SpectraWAVE performed a series of bench tests to demonstrate its system meets its performance specifications using production-equivalent, finished, sterilized, and preconditioned product. Comprehensive verification and validation activities were successfully completed, raising no new issues of safety or effectiveness. All testing passed the acceptance criteria.

7.7 Animal Testing:

SpectraWAVE conducted a GLP animal study to evaluate acute performance and vascular injury following deployment of the SpectraWAVE Imaging Catheter in a porcine coronary artery model.

Overall, the test device met the acceptance criteria for the study and should be considered to have acceptable acute performance and safety.

7.8 Summative Usability Testing:

Usability evaluation was conducted to establish that the SpectraWAVE 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 SpectraWAVE 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:

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