DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 17, 2017

SpectralMD, Inc.
J. Michael DiMaio, MD
CEO
2515 McKinney Avenue
Dallas, TX 75201

Re: K163339
Trade Device Name:SpectralMD DeepView Wound Imaging System 2.0
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: July 20, 2017
Received: July 24, 2017

Dear Dr. DiMaio:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163339

Device Name
Spectral MD DeepView™ Wound Imaging System 2.0

Indications for Use *(Describe)*

The SpectralMD™ DeepView™ Wound Imaging System 2.0 is an optical imaging device intended for studies of blood flow in the microcirculation. The DeepView system is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics. In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery), chronic wounds, decubitus ulcers and diabetic ulcers.

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.

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SpectralMD
Seeing the Unknown

510(k) Summary

Submitted by:

SpectralMD, Inc.
2515 McKinney Ave., Suite 1000
Dallas, Texas 75201
855-436-2278

Date Prepared:	August 11,, 2017
Contact Person:	J. Michael DiMaio, M.D. / CEO 855-436-2278
Trade Name:	SpectralMD™ DeepView™ Wound Imaging System 2.0
Common Name:	Extravascular Blood Flow Probe
Classification Name:	Extravascular Blood Flow Probe
Reference:	21 CFR §870.2120– Class II
Product Code:	DPT

Predicate Devices:

K124049: DeepView Digital Video Physiological Portable Imaging System (Primary)
K123216: EasyLDI Microcirculation Camera (Additional Predicate)

Device Description:

The DeepView System 2.0 is a prescription device that utilizes the principles of non-contact photoplethysmography (PPG) to capture images of tissue blood perfusion. This is accomplished by measuring the optical properties of tissues and blood as they vary in response to changing hemodynamic conditions. The device's software combines real-time digital analysis based on the interaction of light with vascular tissues below the skin's surface to produce 2-D color images on a touch-screen display depicting relative blood perfusion. The DeepView System consists of a Camera Head with LED optics, an Articulating Arm for Camera Head positioning, a Touch-Screen Display for image viewing, and for accessing and interacting with the Graphical User Interface (GUI). All components are integrated on a Mobile Cart that houses the hardware/software, uninterruptable power supply (UPS), and allows for transport between use environments. The DeepView System 2.0 is AC powered with a backup UPS, and is for use in healthcare/hospital facilities.

Indications for Use:

The SpectralMD™ DeepView™ Wound Imaging System 2.0 is an optical imaging device intended for studies of blood flow in the microcirculation. The DeepView System is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics. In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery), chronic wounds, decubitus ulcers, and diabetic ulcers.

Technological Comparison:
The DeepView System 2.0 utilizes the same photoplethysmography (PPG) technology as the original DeepView device (primary predicate) in which PPG technology utilizes light to detect pulsatile blood flow in patients and then provides 2D color images of relative perfusion. The devices are software controlled, consist of the same system components, and achieve the output in the same manner. Differences between the devices include an updated indication for use, software upgrades, broadband illumination, hardware and ergonomic improvements. The table below presents a comparison of key technological characteristics:

TECHNOLOGICAL COMPARISON						
	Subject device		**Primary Predicate**		**Additional Predicate**	
Feature	**DeepView System 2.0**		DeepView Digital Video Physiological Portable Imaging System		Aimago EasyLDI and EasyLDI Studio	
510(k) #	K163339		K124049		K123216	
Common Name	Extravascular Blood Flow Probe		Extravascular Blood Flow Probe		Laser Doppler Imager Viewing Software for desktop computer (Accessory)	
Regulation	21 CFR Part 870.2120		21 CFR Part 870. 2120		21 CFR Part 870.2120	
Prod. Code	DPT		DPT		DPT	LXN
Submission & Class	510(k) Class II		510(k) Class II		510(k) Class II	510(k) Unclassified
Technology	PPG		PPG		Laser Doppler /2-D Image	
Illumination	LED		LED		Class 2M Laser	
Wavelength	400-900nm		870 nm		808 nm	
-PPG	850 nm	Optical intensity 0.98 mW/cm^2	870 nm	Optical intensity 1.73 mW/cm^2	NA	
-Color Ref. Image	400-900 nm	3.71 mW/cm^2	NA – Black & White		532-635 nm	
-Guiding Beams	524 nm	0.16 mW/cm^2	NA		Green focus lasers: 532 nm Red line lasers: 635 nm	
Control Mech.	Software		Software		Software	
Data Analysis	Proprietary Software Algorithm		Proprietary Software Algorithm		Proprietary Software Algorithm	
Size	28.5 x 40 x 67”		24 x 24x 61”		unknown	
Weight	292 lbs		150 lbs		unknown	
Acquisition Modes	Relative Perfusion in Microcirculation via PPG imaging		Relative Perfusion in Microcirculation via PPG imaging		Relative Perfusion in Microcirculation via laser Doppler flux	

Indications for Use	The SpectralMD™ DeepView™ Wound Imaging System 2.0 is an optical imaging device intended for studies of blood flow in the microcirculation. The DeepView system is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics**.** In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery), chronic wounds, decubitus ulcers, and diabetic ulcers	The SpectralMD DeepView System is intended for studies of blood flow in the microcirculation. The DeepView System is suitable for a wide variety of clinical applications including plastic surgery, diabetes, dermatology, vascular surgery, wound healing, neurology, physiology, neurosurgery and anesthetics.	The Aimago EasyLDI Microcirculation Camera is intended for blood flow measurements in the microcirculation. In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery) and hand surgery. EasyLDI Studio is intended as offline viewer applications for snapshots, videos, and references recorded with the Aimago EasyLDI Microcirculation Camera.
Software Modules	Blood Flow Study, Burn Wounds, Diabetic/Ischemic Wounds, Decubitus Wounds, Chronic Wounds	None	Burn Wounds, Skin Flaps (plastic and reconstructive surgery and hand surgery.
User Interface	Graphical Touch Screen User Interface with keyboard and mouse input, mechanical buttons	User Interface with keyboard and mouse input, mechanical buttons	Graphical Touch Screen User Interface with keyboard and mouse input, mechanical buttons
Image Speed for Full Scan	27 sec	30 sec	Unknown
Image Speed for Processing	30 sec	30 sec	Unknown
Pulse Rate Detection	60-180 bpm	60-200 bmp	Yes; unknown rate detection
Camera Resolution	1280 x 1024	1024 x 512	480 x 480 pixels

The updated indications for use of the DeepView 2.0 include a listing of wound types commonly presenting within the cleared clinical applications of the original DeepView device (primary predicate) and do not indicate a new intended use or new target population. Software updates improve processing efficiency and an improved user interface that includes specific wound modules for facilitating patient/wound documentation (similar to the additional predicate cited). The DeepView 2.0 uses broadband illumination between 400-900 nm versus a single wavelength for the primary predicate. This broadband illumination is included so that in addition to PPG measurements (850 nm), the device will display a color reference image (400-900 nm), rather than a black and white reference image produced by the primary predicate. Further, the broadband range permits the addition of green guiding beams to facilitate camera placement above the imaging site. Note: the wavelengths used to capture PPG images are similar between the DeepView System 2.0 (850 nm) and the original DeepView device (870 nm). This minor difference in wavelength is inconsequential in obtaining PPG images, and remains within the non-

harmful range. Additional differences between the DeepView 2.0 and the primary predicate also include a high-resolution camera, a larger, HD touch-screen monitor, and ergonomic improvements to the Mobile Cart. These differences are not considered to raise new issues of safety and effectiveness.

Summary of Testing

The DeepView System 2.0 has been subjected to comparative testing against the original DeepView system (primary predicate) in order to demonstrate that DeepView 2.0 is capable of detecting the pulsatile component of fluid flow in an equivalent manner to that of the primary predicate. In this testing, the device's ability to detect pulsatile fluid flow, frequency detection, and capability to detect pulsatile flow under conditions simulating physiological properties of blood flow in human tissues was evaluated. The results demonstrated the ability of the DeepView 2.0 to identify the 2% alternating change (AC) modulation that is consistent with the tissue-volume change in human tissue resulting from blood flow; to identify the AC modulations at various frequencies within the frequencies of the human heart rate; and to detect fluid flow beneath the surface of an optically dense medium. These results demonstrate that the DeepView System 2.0 performs in an equivalent manner to the original DeepView System (primary predicate).

The DeepView System 2.0 was also been evaluated for electrical safety and electromagnetic compatibility and was found to meet AAMI/ANSI ES60601-1:2005/(R) 2012 & A1:2012; IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 and IEC 60601-1-2 (2007)/(R) 2012. The DeepView 2.0 has been designed in accordance with FDA guidance on human factors and usability engineering and subjected to usability testing validation. No clinical performance data were needed to support substantial equivalence. The results of the testing performed demonstrate the DeepView Wound Imaging System 2.0 to be substantially equivalent to the predicate and does not introduce any new issues of safety and effectiveness.

Conclusion

The SpectralMD DeepView Wound Imaging System 2.0 is substantially equivalent to the predicate devices based upon the indication for use, technological characteristics, and the data submitted.