Apollo Medical Optics, Ltd.
℅ Feng-Yu Lee
Principal Regulatory Consultant
Elite BioMedical Consulting, Inc.
29122 Rancho Viejo Rd., Suite 212
San Juan Capistrano, California 92675

September 2, 2020

Re: K201552
Trade/Device Name: ApolloVue S100 Image System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: June 9, 2020
Received: June 10, 2020

Dear Feng-Yu Lee:

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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201552

Device Name
ApolloVue S100 Image System

Indications for Use *(Describe)*
ApolloVue S100 Image System is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.

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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510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is:

1. Submitter Identification:

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Date Summary Prepared: June 9, 2020

2. Name of the Device:

ApolloVue S100 Image System

3. Common or Usual Name: System, Imaging, Optical Coherence Tomography (OCT)

Product Code	Classification	Regulation Section	Panel
NQQ; System, Imaging, Optical Coherence Tomography (OCT)	Class II	21 CFR 892.1560	General & Plastic Surgery

4. Device Description:

The ApolloVue S100 Image System consists of a cart-mounted imaging console and robotic arm imagine probe with reusable non-sterile scanning window cap. The light source module, main control board, power supply and personal computer are configured inside the cart. The probe contains interferometer comprise of optics and electronics. The system user interface allows the viewing, capture, review and export of images.

With AMO single-crystal fiber light source, the ApolloVue S100 Image System provides near-infrared broadband optical output and cellular images with an axial resolution around one micron. The ApolloVue S100 Image System employs full-field OCT (FF-OCT) utilizing a camera for parallel detection to avoid latera scanning and thus increases the scanning speed. The ApolloVue S100 Image System provides both high resolution B-scan and en face imaging with decent scanning speed. The cross-sectional image can be shown in real-time without reconstruction after whole volume is scanned. In addition, by scanning an en-face image plane with the coherence and confocal

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gates matched, the ApolloVue S100 Image System does not suffer from depth-of-field limitations present in standard OCT and can achieve micron scale transverse image resolutions. With a simple optical switch, user can switch between two modes to improve the efficiency of lesion examination and gather more structure information.

5. Indications for Use:

ApolloVue S100 Image System is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.

6. Predicate Device Information:

ApolloVue S100 Image System is substantially equivalent to the following device:

Name:	VivoSight Topical OCT System
Device Company:	Michelson Diagnostics Ltd
510(K) Number:	K093520

7. Comparison to Predicate Device:

As shown in the following comparison table, the ApolloVue S100 Image System has the same intended use and similar technical characteristics as its predicate device (K093520). The minor technical differences between the ApolloVue S100 Image System and its predicate do not rise new or different questions of safety and effectiveness.

Specification	**Subject Device – ApolloVue S100 Image System**	**Predicate Device – VivoSight Topical OCT System (K093520)**
Similarities & Differences		
Regulation Number	21 CFR 892.1560	Same
Class	II	Same
Product Code	NQQ	Same
Device Class/Name	System, Imaging, Optical Coherence Tomography (OCT)	Same
Indication for Use	ApolloVue S100 Image System is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing two-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.	VivoSight is a Multi-Beam Optical Coherence Tomography (OCT) system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body.

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Measurement Technique	Optical Coherence Tomography	Optical Coherence Tomography
Near-Infrared Wavelength (700-1400 nm)	Yes	Yes
Light Source Center Wavelength	750 nm	1300 nm
Lateral Scanning Range	0.5 mm	5.0 mm
Axial Scanning Range	0.35 mm	Up to 2.0 mm
Lateral Resolution	1.0 μm	< 7.5 μm
Axial Resolution	1.5 μm	< 5 μm
Scan Time	En face: 6 fps B-scan: 0.4 fps	> 6 fps
Optical Radiation Safety	Class 1 Laser	Same
Power Supply	100-240 V 50-60 Hz	110-132 V 50-60 Hz

8. Technology Characteristics:

The ApolloVue S100 Image System has the same intended use and similar technological characteristics as the predicate, VivoSight Topical OCT System (K093520). Both the ApolloVue S100 Image System and the predicate device utilize Optical Coherence Tomography to create high resolution cross-sectional and en face real-time images of tissue microstructure. The ApolloVue S100 Image System and the predicate device both use near infrared light to produce OCT images with comparable axial and lateral resolution. The comparison of the ApolloVue S100 Image System and its predicate device shows that their technological characteristics are similar and the minor differences do not raise new or different question of safety and effectiveness.

9. Discussion of Performance Data for Determination of Substantial Equivalence are as follows:

The ApolloVue S100 Image System is designed and tested to be in compliance with international standards concerning safety for electrical safety, electromagnetic compatibility, biocompatibility, disinfection, mechanical safety, and laser safety. A series of tests were conducted to assess the performance and safety of the ApolloVue S100 Image System. All acceptance criteria were met, supporting substantial equivalence for the subject device. A brief summary of the performance testing is described below.

The system uses a laser that is limited in power to meet the requirements of a class 1 laser device in accordance with IEC 60825-1. The handheld probe has been designed to be a reusable component and to support cleaning and disinfection. The reusable probe tip (scanning window cap) is designed using materials that adhere to the requirements for skin surface limited contact (< 24 hours) and to be replaced after 25 times of cleaning and disinfection. The reusable scanning window cap has been tested for biocompatibility per ISO 10993 based on the intended use.

The system image performance has been tested to evaluate the performance of the ApolloVue S100 Image System to demonstrate the imaging capabilities for the visualization of skin microstructure in vivo. Images were taken using both B-scan and En face modes of the ApolloVue S100 Image

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System from different body sites of human subjects. Typical patterns of skin can be linked to image patterns visible in the B-scan- and En face-images of the ApolloVue S100 Image System.

10. Substantial Equivalence Conclusions:

The ApolloVue S100 Image System has the same intended use and similar indications, technological characteristics, and principles of operation as the predicate device, VivoSight Topical OCT System (K093520). The minor technical differences between the ApolloVue S100 Image System and the predicate device do not rise new or different questions of safety and effectiveness. Performance data demonstrate that the ApolloVue S100 Image System is substantially equivalent to the predicate device.