Lightmed USA, Inc.
℅ Ms. Angel Hsieh
Regulatory Affairs Administrator
1130 Calle Cordillera
SAN CLEMENTE CA 92673

April 13, 2018

Re: K170761
Trade/Device Name: LIGHTSonic B | UBM
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: March 1, 2018
Received: April 2, 2018

Dear Ms. Hsieh:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K170761

Device Name
LIGHTSonic B | UBM

Indications for Use *(Describe)*

LIGHTSonic B | UBM is a non-invasion diagnostic ophthalmic ultrasound instrument specifically designed for measurements inside the ocular structures including orbital, anterior and posterior segment of eye.

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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Section 5 510(k) Summary

I. SUBMITTER

LIGHTMED USA, INC.

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Contact Person: Katrina Hsu/Regulatory Affairs Administrator

Date Prepared: June 30, 2017

II. DEVICE

Trade name: LIGHTMED Ultrasound System
Model name: LIGHTSonic B｜UBM

Classification name: System, Imaging, Pulsed Echo, Ultrasonic

Classification Panel: Radiology

Regulation number: 892.1560, 892.1570

Product code: IYO, ITX

III. PREDICATE DEVICE

Substantial equivalence to the following predicate device is as follows:

Sonomen Inc. Vupad	K140199	Decision Date:04/01/2014

IV. DEVICE DESCRIPTION

The LIGHTMED Ultrasound System is a portable ultrasound biometric ruler intended for use in ophthalmic applications. The system allows for the measurement of several key ocular features including axial length (AXL), anterior chamber depth. The device is used by coupling the probe / transducer to the eye either through direct contact or immersion methods. Available modes are biometric B-scan and UBM.

The B-Scan mode produces a live, two-dimensional image to facilitate the identification and measurement of ocular pathologies in the posterior-chamber of the eye, particularly when view of the chamber is obscured, such as is the case with cataracts.

The UBM mode can be used with a 35 MHz or a 50 MHz transducer. Because of the higher frequency of the transducer, it is expected that its greatest field of application will be in visualizing the anterior segment, because the focus area is about 11 mm from the transducer plane. The system will visualize other parts of the eye, but the resolution is not as high.

LIGHTMED Ultrasound System is a stand-alone system that runs on a Windows 10 platform and may be networked (by the user) for interface with electronic medical records systems, printing, and other purposes. The system consists of the LIGHTSonic B|UBM console, ultrasound probe(s) and transducer, and foot pedal.

V. INDICATIONS FOR USE

The LIGHTMED Ultrasound System is a non-invasion diagnostic ophthalmic ultrasound instrument specifically designed for measurements inside the ocular structures including orbital, anterior and posterior segment of eye.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A summary listing of the LIGHTMED Ultrasound System design characteristics that are identical as the predicate is provided below:

product name	LIGHTMED Ultrasound System	Vupad System
model name	LIGHTSonic B｜UBM	Vupad

manufacturer	LIGHTMED USA, INC.	Sonomed Inc.
510(k) number	K170761	K140199
intended use	* make measurements inside the ocular structures including - orbital structure - anterior segment of eye - posterior segment of eye	*visualize the interior of the eye *make measurement inside the eye such as - axial length - anterior chamber depth - lens thickness
hard drive	128 GB C-fast card	128 GB SSD solid-state drive
operating voltage	100 - 240 VAC, 50/60 Hz auto-switching medical-grade power supply	100 - 240 VAC, 50/60 Hz auto-switching medical-grade power supply
control interface	Operator uses LCD multi-touch control panel and foot pedal switch to collect exam data.	Operator uses LCD multi-touch control panel and foot pedal switch to collect exam data.
EMR connectivity	DICOM	DICOM
general method of operation	* Echoes converted to images on a screen * Measurement made by time delays	* Echoes converted to images on a screen * Measurement made by time delays
digital system	Echoes converted into digital pulses, all operation carried out digitally.	Echoes converted into digital pulses, all operation carried out digitally.

probe design	* B-scan: sealed probes with focused transducer * UBM: water path probe with interchangeable focused transducer	* B-scan: sealed probes with focused transducer * UBM: water path probe with interchangeable focused transducer
pulse repetition frequency	B-scan & UBM: 2560 Hz	B-scan & UBM: 2560 Hz
export image	PDF ; JPEG; AVI	PDF ; JPEG; AVI
printer	Any Windows-compatible printer (separate)	Any Windows-compatible printer (separate)

A summary listing of the LIGHTMED Ultrasound System design characteristics differ from the predicate is provided below:

product name	LIGHTMED Ultrasound System	Vupad System
model name	LIGHTSonic B｜UBM	Vupad
manufacturer	LIGHTMED USA, INC.	Sonomed Inc.
510(k) number	K170761	K140199
unit	12.75'' w x 3'' d x 8'' h (32.3 x 7.6 x 20.3 cm)	13.3'' w x 8.0'' d x 2'' h
device system	The LIGHTSonic B｜UBM is an advanced microprocessor-controlled ultrasonic system, composed of the following sub-systems: * LCD control panel	Vupad is an innovative ultrasonic system, composed of the following sub-systems: * LCD touch screen * sealed A-probe * B-probes

	* B-scan probes * UBM probes * footswitch	* UBM probes * foot pedal
operating system	Microsoft Windows 10	Microsoft Windows 8
annotation	image annotation with six tools: orientation, angle, distance, pointer, area, text	automatic annotation of images and video clips
scan controls	fully adjustable time gain control (TGC)	fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain (e-gain)
compliance standard	* US Federal Performance Standards 21 CFR 892.1560 for Class II Ultrasonic products - AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 - IEC 60601-1-2: 2007 - IEC 60601-1-6:2013 - IEC 60601-2-37:2007 - ISO 14971:2007 - IEC 62366:2014	* US Federal Performance Standards 21 CFR 892.1560 and 1570 for Class II Ultrasonic products - IEC 60601-1 - EN/IEC 60601-1-2 (2001) - IEC 60601-2-37

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The patient contact components for B-scan and UBM probes along with LIGHTMED Ultrasound System conducted cytotoxicity, sensitization, and irritation testing in accordance with FDA guidance- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* The patient contact materials for B-scan and UBM probes fall into surface device and the contact is mucosal membrane. Contact duration is A-limited. The results showed patient contact materials conform to ISO 10993-1, 10993-5 and ISO 10993-10.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on LIGHTMED Ultrasound System. It complies with the following applicable federal and international safety and performance standards.

* AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text)
* IEC 60601-1-2:2007
* IEC 60601-1-6:2013
* IEC 60601-2-37:2007
* ISO 14971:2007
* IEC 62366:2014

Software verification and validation testing

Software verification and validation testing were performed, and documents are established as recommended by FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. The software for this device was considered as a Moderate Level of Concern, since failures or latent flaws in the software could directly result in non-serious injury to the patient, operator, and/or bystander.

Measurement accuracy

LIGHTMED Ultrasound System has been validated and is safe and effective for the functions described in the indications for use.

VIII. CONCLUSIONS

The LIGHTMED Ultrasound System is substantially equivalent to the predicate devices in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties. The LIGHTMED Ultrasound System is designed to comply with applicable federal and international safety and performance standards. There are no new safety and effectiveness issues being raised.