Lightmed USA, Inc.
℅ Hedy Chiang
Regulatory Affairs Administrator
1130 Calle Cordillera
SAN CLEMENTE CA 92673

July 1, 2019

Re: K183173
Trade/Device Name: LIGHTMED Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: June 4, 2019
Received: June 5, 2019

Dear Hedy Chiang:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K183173

Device Name
LIGHTMED Ultrasound System

Indications for Use *(Describe)*
LIGHTMED Ultrasound System is a non-invasion diagnostic ophthalmic ultrasound instrument specifically designed for measurements inside the ocular structures including orbital, anterior, posterior segment of eye and axial length for determination of IOL Power.

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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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

System: LIGHTMED Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						(A- mode) N
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

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System: LIGHTMED Ultrasound System Transducer: 10MHz A-scan Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							(A- mode) N
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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6-3

N = new indication; P = previously cleared in K170761

System: LIGHTMED Ultrasound System Transducer: 12MHz, 20MHz B-scan Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

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6-4

N = new indication; P = previously cleared in K170761

System: LIGHTMED Ultrasound System Transducer: 35MHz, 50MHz UBM Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

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Section 7 510(k) Summary

K183173

I. SUBMITTER

LIGHTMED USA, INC.
1130 Calle Cordillera, San Clemente, CA 92673, U.S.A.
T: +1-949-218-9555
F: +1-949-218-9556
Contact Person: Hedy Chiang/Regulatory Affairs Coordinator
Date Prepared: Oct 26, 2018

II. DEVICE

Trade name: LIGHTMED Ultrasound System
Model name: LIGHTSonic Ultrasound
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:

Primary Predicate Device	LIGHTMED USA, INC LIGHTSonic B｜UBM	K170761	Decision Date:04/13/2018
Reference Device	Sonomed Inc. Vupad	K140199	Decision Date:04/01/2014

IV. DEVICE DESCRIPTION

The LIGHTMED Ultrasound System (model name: LIGHTSonic Ultrasound) 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 A scan, biometric B-scan and UBM.

The A-scan mode of the system features a live A scan trace with storage for up to four scans. There are four (auto/manual) examination modes that use 9 different tissue velocities to calculate individual intraocular distances within the eye (AXL, ACD, Lens, and Vitreous). Other features include: post examination review of scans & measurement; four IOL formulas for lens power calculations; an immersion scanning capability for zero corneal compression of the eye while scanning and storage for up to five different user files.

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 console, ultrasound probe(s) and transducer, and foot pedal.

V. INDICATIONS FOR USE

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

determination of IOL Power.

System: LIGHTMED Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						(A- mode) N
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

System: LIGHTMED Ultrasound System Transducer: 10MHz A-scan Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							(A- mode) N
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
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	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

System: LIGHTMED Ultrasound System Transducer: 12MHz, 20MHz B-scan Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

System: LIGHTMED Ultrasound System Transducer: 35MHz, 50MHz UBM Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared in K170761

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

Product name	LIGHTMED Ultrasound System	LIGHTMED Ultrasound System	VuPad
Model name	LIGHTSonic Ultrasound	LIGHTSonic B ｜UBM	VuPad
Manufacturer	LIGHTMED USA, INC.	LIGHTMED USA, INC.	Sonomed Inc.
510(k) number		K170761	K140199
Intended use	* visualize the interior of the eye * make measurement inside the eye such as - axial length - anterior chamber depth - lens thickness	* 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 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	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.	Operator uses LCD multi-touch control panel and foot pedal switch to collect exam data.
EMR connectivity	DICOM	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	* 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.	Echoes converted into digital pulses, all operation carried out digitally.
Probe design	* A-scan: closed fixed single-element with internal fixation light * 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	* A-scan: closed fixed single-element with internal fixation light * B-scan: sealed probes with focused transducer * UBM: water path probe with interchangeable focused transducer
Pulse repetition frequency	A-scan: 5880 Hz B-scan & UBM: 2560 Hz	B-scan & UBM: 2560 Hz	A-scan: 5880 Hz B-scan & UBM: 2560 Hz
Export image	PDF ; JPEG; AVI	PDF ; JPEG; AVI	PDF ; JPEG; AVI
Printer	Any Windows-compatible printer (separate)	Any Windows-compatible printer (separate)	Any Windows-compatible printer (separate)

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

Product name	LIGHTMED Ultrasound System	LIGHTMED Ultrasound System	VuPad
Model name	LIGHTSonic Ultrasound	LIGHTSonic B｜UBM	VuPad

Manufacturer	LIGHTMED USA, INC.	LIGHTMED USA, INC.	Sonomed Inc.
510(k) number	new	K170761	K140199
Unit	12.75" w x 3" d x 8" h (32.3 x 7.6 x 20.3 cm)	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 Ultrasound is an advanced microprocessor-controlled ultrasonic system, composed of the following sub-systems: * LCD control panel *A mode probe * B-scan probes * UBM probes * foot pedal switch	The LIGHTSonic Ultrasound is an advanced microprocessor-controlled ultrasonic system, composed of the following sub-systems: * LCD control panel * B-scan probes * UBM probes * foot pedal switch	Vupad is an innovative ultrasonic system, composed of the following sub-systems: * LCD touch screen * sealed A-probe * B-probes * UBM probes * foot pedal
Operating system	Microsoft Windows 10	Microsoft Windows 10	Microsoft Windows 8
Annotation	image annotation with six tools: orientation, angle, distance, pointer, area, text	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 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	* 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	* 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

	A2:2010/(R)2012 - IEC 60601-1-2: 2014 - IEC 60601-1-6:2013 - IEC 60601-2-37:2007 - ISO 14971:2007 - IEC 62366:2014	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	

VII. PERFORMANCE DATA

The following performance data were provided to support substantial equivalence determination.

Biocompatibility testing

The patient contact components for A-scan, B-scan and UBM probes along with LIGHTMED Ultrasound System were subjected to 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 A-scan, B-scan and UBM probes are surface contact device with mucosal membrane. Contact duration is limited to less than 30 minutes. (which is shorten than 24 hours mentioned in ISO 10993 A-limited.) The Biocompatibility testing results showed patient contact materials of LIGHTMED Ultrasound System conform to ISO 10993-1, 10993-5, ISO 10993-10, and ISO 10993-11.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on LIGHTMED Ultrasound System, according to 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 60601-1-2:2014
* IEC 60601-1-6:2013
* IEC 60601-2-37:2007
* ISO 14971:2007
* IEC 62366:2014

The testing results demonstrate that LIGHTMED Ultrasound System comply with all the

required standards.

Software verification and validation testing

The software for LIGHTMED Ultrasound System 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. Software verification and validation were performed, keep as recommended by FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Measurement accuracy

LIGHTMED Ultrasound System has been validated and is safe and effective for the intended use 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.