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

July 29, 2015

Sony Electronics Incorporated
Mr. Amarjit Jowandha
Head, Quality Assurance, Regulatory Affairs & Compliance
1 Sony Drive, Mail Stop 3C5
Park Ridge, New Jersey 07656

Re: K150377
Trade/Device Name: Sony LMD-X310S LCD Monitor, Sony LMD-X310MD LCD Monitor, Sony LMD-X310NB LCD Monitor, Sony LMD-X550S LCD Monitor, Sony LMD-X550MD LCD, Sony LMD-X550NB LCD Monitor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 19, 2015
Received: June 22, 2015

Dear Mr. Jowandha:

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,

Joshua C. Nipper -S

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)*
K150377

Device Name
Sony LMD-X310S LCD Monitor, Sony LMD-X310MD LCD Monitor, Sony LMD-X310NB LCD Monitor,
Sony LMD-X550S LCD Monitor, Sony LMD-X550MD LCD Monitor, Sony LMD-X550NB LCD Monitor

Indications for Use *(Describe)*
The LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic / laparoscopic camera systems and other compatible medical imaging systems.
The LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

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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"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."

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

510(k) Number: K150377

5.1 Applicant Information

Date Prepared:	March 12, 2015
Company Name and Address:	Sony Electronics, Inc. Sony Medical Systems Division 1 Sony Drive, Mail Stop 3C5 Park Ridge, NJ 07656 United States
Contact Person:	Mr. Amarjit "Andy Singh" Jowandha Head, Quality Assurance, Regulatory Affairs & Compliance Phone: +1 (201) 930-6078 FAX: +1 (201) 358-4977 Email: amarjit.jowandha@am.sony.com

5.2 Device Information

Device Type:	LCD Monitor
Regulation Description:	Endoscope and Accessories
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Device Class:	II
Device Name:	LMD-X310S, LMD-X310MD, LMD-X310NB, LMD-X550S, LMD-X550MD and LMD-X550NB

5.3 Predicate Devices

The legally marketed devices to which substantial equivalence is being claimed are:

510(k) Number:	K113203
Applicant:	Sony Electronics Inc.
Device Name:	SONY LMD-2451MT LCD MONITOR
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Device Class:	II

5.4 Device Description

The Sony LMD-X310S, LMD-X310MD and LMD-X310NB are 31 inches LCD monitors, and LMD-X550S, LMD-X550MD and LMD-X550NB are 55 inches LCD monitors with an advanced display technology, designed for use in medical environments. These monitors provide 4K resolution 2D color video displays of images from a surgical endoscope, laparoscopic camera system, and other compatible medical imaging systems. They are suitable for environments such as operating rooms, surgical centers, clinics, doctor's offices, and similar locations.

LMD-X310S、LMD-X310MD and LMD-X310NB are operated by DC power supply and supplied with a dedicated AC adaptor, AC-300MD. LMD-X310MD is SONY brand model, LMD-X310S is a model for a specified customer and LMD-X310NB is for unspecified customers.

MD-X550S、LMD-X550MD and LMD-X550NB are operated by AC power supply. LMD-X550MD is SONY brand model, LMD-X550S is a model for a specified customer and LMD-X550NB is for unspecified customers.

Key features include:

- Large and 4K Screen

  The 4K ultra high resolution on 31 inch and 55 inch size large screen offers high picture quality.

- Wide color gamut

  The LCD panel and signal processing technology realize wide color gamut.

- Clear and High-contrast View

  The OptiContrast Panel™ achieves clear, high-contrast images by controlling reflection and minimizing light dispersion in the LCD panel. It also helps to eliminate dew condensation in the panel.

- A.I.M.E.™ (Advanced Image Multiple Enhancer)

  There are two modes in A.I.M.E function, named as "Structure Enhancement mode" and "Color Enhancement mode". Users can select four levels for Structure Enhancement mode and eight levels for Color Enhancement mode, depending on user's preference. By utilizing A.I.M.E function, users can expect the following effectiveness on display image.

  - ✓ Color Enhancement Function
    - Color Enhancement Function clarifies color tone of the specific color (such as red) object.
  - ✓ Structure Enhancement Function
    - Structure Enhancement Function improves recognition of the object's outline.
    - Visibility gets clear to easily see objects.

- Narrow Bezel

  The narrow bezel achieves a wider display area, even with the compact body.

- Ergonomic Design

  The easy-to-hold design enables the user to adjust monitor position easily.

- User-friendly Control Panel

  LED navigated operation enables easy setting. The user can assign CUSTOM buttons to commonly used functions.

- Variety of Display Format

  A variety of display format – including Rotation Image, Side-by-Side, Picture-in-Picture, and Picture-out-Picture – can be selected easily by simply pressing buttons.

- Easy to Clean

  The flat surface allows the user to easily wipe liquids and gels off the LCD panel and control buttons, facilitating cleanliness and disinfection.

- Installation-friendly Cabling

  All the connectors face downwards, allowing for easy and organized cable connection.

5.5 Intended Use/Indications for Use

The LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic / laparoscopic camera systems and other compatible medical imaging systems.
The LCD Monitor is a wide-screen, high-definition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

5.6 Technological Characteristics

The subject device compares to the legally marketed devices as follows:

Device	**Subject Device**		**Predicate device**
	LMD-X310S LMD-X310MD LMD-X310NB	**LMD-X550S LMD-X550MD LMD-X550NB**	**SONY LMD-2451MT LCD MONITOR**
Intended environment	Hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments		Hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments
Intended users	Doctors and assistants		Doctors and assistants
Compatibility with other devices	Surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems		Surgical endoscopic/laparoscopic camera systems and other compatible medical imaging

5.0 510(k) Summary

Sony Electronics Inc.
LCD Monitor
LMD-X310S, LMD-X310MD, LMD-X310NB, LMD-X550S, LMD-X550MD and LMD-X550NB

Device	Subject Device		Predicate device
	LMD-X310S LMD-X310MD LMD-X310NB	**LMD-X550S LMD-X550MD LMD-X550NB**	**SONY LMD-2451MT LCD MONITOR**
			systems
Power	AC 100-240 V/50-60 Hz		AC 100-240 V/50-60 Hz
Dimensions (excluding maximum protrusions)	753.8×456.4×69.3mm	1264.6×771.5×85.5mm	602.4/386.2/110 mm
Display dimension	2D		2D / 3D
Input signals	DVI-D, HDMI, 3G/HD/SD-SDI		DVI-D, HD15, RGB/Component, Y/C, Composite SDI 4:2:2 (optional) HD/D1-SDI (optional) NTSC/PAL :Y/C, Composite (optional) Analog Component (optional) 3G/HD/SD-SDI (optional) DVI-D (optional)
Output signals	DVI-D, 3G/HD/SD-SDI		Composite output connector Y/C output connector RGB/component output connectors External synchronized output connector
Display device	LCD panel (IPS)		LCD panel (IPS)
Backlight device	LED		CCFL
Viewing angle	Right>89[deg] (CR>10) Left>89[deg] (CR>10) Up>89[deg] (CR>10) Down>89[deg] (CR>10)		Right>89[deg] (CR>10) Left>89[deg] (CR>10) Up>89[deg] (CR>10) Down>89[deg] (CR>10)
Active screen size	697.958(H)×368.064(V) mm	1209.573(H)×680.385(V) mm	518.4(H)×324.0(V) mm
Resolution	4096×2160 pixels	3840×2160 pixels	1920×1200 pixels
Maximum Luminance	≥550[cd/m2]	≥330[cd/m2]	≥200[cd/m2]
Color Gamut	Avg. 135% of sRGB	Avg. 135% of sRGB	Avg. 102% of sRGB
Picture enhancement	A.I.M.E. function		NA

Device	**Subject Device**		**Predicate device**
	LMD-X310S LMD-X310MD LMD-X310NB	**LMD-X550S LMD-X550MD LMD-X550NB**	**SONY LMD-2451MT LCD MONITOR**
Refresh rate	50/60 [Hz]	100/120 [Hz]	50/60 [Hz]
Frame rate	50/60 [fps]		50/60 [fps]
Display format	Normal Multi display Flip display		Normal Multi display Mirror image
Performance Standards	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 62304 ISO 14971		IEC 60601-1 EN 60601-1-2 ISO 14971

As demonstrated in the above comparison table , the subject and predicate devices have similar technological characteristics such as intended environments, intended users, compatibility with other endoscopic/laparoscopic devices, power ratings, video input and output signals, frame rate, display format and performance standards.

The subject and predicate devices also have differences in technological characteristics, such as dimensions and active screen size, display dimension, video input and output signals, backlight devices, resolution, refresh rate, and standards. We do not consider these differences to make the subject devices less safe and effective than the predicate device for their intended use and we do not consider these differences to raise different questions of safety and effectiveness.

5.7 Non-Clinical Performance Data

The subject devices demonstrate conformance with the following recognized standards:

- ANSI/AAMI ES60601-1
- IEC 60601-1-2
- IEC 62304
- ISO 14971

The subject devices have additionally undergone bench testing as part of required performance verification and validation activities. Results show that the subject device has met pre-defined design and performance acceptance criteria. Results of all non-clinical testing support the safety and effectiveness of the subject devices.

5.8 Clinical Performance Data

No clinical data was collected to support substantial equivalence between the subject and predicate devices.

5.9 Conclusions

Based on the above information and all data provided in this submission, the comparison of intended uses, technological characteristics, and non-clinical performance testing demonstrates that the subject devices are substantially equivalent to the predicate device identified in this submission.