K120611

510(k) Summary
for
Sony PVM-2551MD OLED Monitor
(per 21 CFR 807.92)

JUN 28 2012

1. APPLICANT / SPONSOR

Sony Electronics Inc.
Sony Medical Systems Division
1 Sony Drive
Park Ridge, NJ 07656

Contact Person: Ms. Aleta Moeller
Telephone: 201-358-4182

Date Prepared: June 8, 2012

2. DEVICE NAME

Proprietary Name: Sony PVM-2551MD OLED Monitor
Common/Usual Name: Monitor
Classification Name: Endoscope and Accessories

3. PREDICATE DEVICE

- Stryker Vision Elect WHDTV, Stryker Endoscopy, K081995

4. DEVICE DESCRIPTION

The Sony PVM-2551MD OLED Monitor is a color video monitor and is intended primarily for use in a medical environment for displaying images captured during minimally invasive and general surgical procedures. The monitor features a 24.5-inch widescreen OLED panel and Sony's TRIMASTER™ technology, which has been developed to provide accurate color reproduction, precision imaging, and quality picture consistency. The monitor employs full high-definition (HD) performance with 1920 x 1080 pixels, an aspect ratio of 16:9, and a pixel efficiency of 99.99%.

OLED (an acronym for Organic Light-Emitting Diode) is a flat-panel screen technology that represents an advance in display technology. It is an emissive technology that generates light from each pixel. The process that is the basis of OLED is electroluminescence. In the Sony PVM-2551MD OLED Monitor, the OLED panel makes use of an organic material, which emits light when an electric current is applied. Being self-emitting, the strength of luminescence can be

controlled by the amount of electric current. This results in quick motion picture response, high contrast and wide dynamic range, and rich color reproduction.

In addition to digital signals, the Sony PVM-2551MD OLED Monitor accepts analog signals and converts them to digital signals.

The Sony PVM-2551MD OLED Monitor is designed with the flexibility to support a variety of formats as standard and also has two built-in option slots to select, expand, and change input/output signals.

5. INTENDED USE

The Sony PVM-2551MD OLED Monitor is intended to provide color video displays of images from surgical camera systems. The PVM-2551MD is a widescreen, high-definition monitor for real-time use during minimally invasive surgical procedures including arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), thorascopy, endoscopy (general, gastroenterological and ENT surgery) and general surgery.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sony PVM-2551MD OLED Monitor has the same overall purpose and function as the predicate device cited above. Both of the systems are intended to provide color video displays of images from surgical camera systems.

7. PERFORMANCE TESTING

Testing of the Sony PVM-2551MD OLED Monitor demonstrated that the device is in compliance with applicable requirements of recognized standards for electromagnetic compatibility and electrical safety.

8. CONCLUSION

Based on the similarities in overall purpose and function, the Sony PVM-2551MD OLED Monitor has demonstrated substantial equivalence to the cited predicate device and any differences do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 28 2012

Sony Electronics, Incorporated
% Aptiv Solutions
Ms. Cynthia Sinclair
Principal Consultant, Regulatory Services, Aptiv Solutions
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K120611
Trade/Device Name: Sony PVM-2551MD OLED Monitor
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ, FET
Dated: June 08, 2012
Received: June 11, 2012

Dear Ms. Sinclair:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120611

Indications for Use

510(k) Number (if known): K120611

Device Name: Sony PVM-2551MD OLED Monitor

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120611