K141454
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JUN 2 6 2014

510(K) SUMMARY FOR THE SONY ELECTRONICS, INC.
Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers

(per 21CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

Sony Electronics Inc.
Sony Medical Systems Division
1 Sony Drive
Park Ridge, NJ 07656
Phone: 201-258-4182
Establishment Registration No: 2246606

Contact:	Brian Zimmer
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2. DEVICE NAME

Proprietary Name:	UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers
Common/Usual Name:	Medical Image Hardcopy Device
Classification Name:	Camera, Multi Format, Radiological
Classification Panel:	Radiology
Device Class:	Class II
Classification Number:	21 CFR 892.2040
Product Code:	LMC

3. PREDICATE DEVICE

The proposed Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Printers are substantially equivalent to the Sony Video Graphic Printer UP-850, cleared under K890826.

4. DEVICE DESCRIPTION

The Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Printers are compact, medical grade black and white printers. The UP-D898MD only accepts digital signal inputs and the UP-X898MD accepts both analog and digital signal inputs.

The printers are designed to be integrated into radiology imaging systems such as

mobile c-arm, ultrasound, cardiac catheterization laboratory and other compatible medical imaging systems and produce 325 dpi high resolution hard copy prints of still images captured by these systems for the patient record purposes or referrals. The images cannot be utilized for diagnostic purposes. Additionally, the UP-X898MD (Hybrid) Printer can store images on a connected USB flash drive.

5. INDICATIONS FOR USE / INTENDED USE

The Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Printers are compact, medical grade black and white printers. The UP-D898MD (Digital) only accepts digital signal inputs and the UP-X898MD (Hybrid) accepts both analog and digital signal inputs. Both printers are designed to be integrated into digital radiology imaging systems such as mobile c-arm, ultrasound, cardiac catheterization laboratory and other compatible medical imaging systems and produce hard copy prints of still images captured by these systems for the patient record or for referrals.

Like the proposed device, the predicate Sony Video Graphic Printer UP-850 are medical grade black and white printers, indicated for use with a wide range of electronic medical diagnostic equipment. The predicate printers were indicated for use with ultrasound and radiological imaging systems and surgical camera systems as well as any other systems that generate the specified video signal output.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The proposed Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Printers represent a technological upgrade to the predicate Sony UP-850 Video Graphic Printer. Both the proposed and predicate devices are thermal printers that provide hard copy images captured by connected imaging systems. The proposed UP-D898MD and UP-X898MD Printers have increased resolution and provide a number of technological features that are an improvement from the predicate devices – including an LCD display panel with LED backlight for controlling settings easily, faster printing speed, and ability to accept digital video input.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The safety and effectiveness of the proposed UP-D898MD and UP-X898MD Graphic Printers have been confirmed by hardware and software testing. The proposed printers comply with applicable requirements of the following standards:

- IEC 60601-1:2005 + C1:2006 + C2:2007
- AAMI/ANSI ES 60601-1: 2005 + C1:2009 + A2:2010
- IEC 60601-1-2:2007

8. Summary of Clinical Testing as Basis for Substantial Equivalence

Not applicable.

9. Summary of Other Information

Not applicable.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The indications for use, principles of operation, and technological characteristics of the proposed Sony UP-X898MD (Digital) / UP-D898MD (Hybrid) Graphic Printers are substantially equivalent to the predicate Sony Video Graphic Printer UP-850 (subject of K890826). Differences between the proposed device and the Sony Video Graphic Printer UP-850 predicate device are limited to minor differences in technological characteristics. These differences do not impact the safety and effectiveness of the printers for the intended use.

The safety and performance of the Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printer for its intended use is demonstrated by non-clinical testing. Based on the evidence provided, Sony Electronics believes that the proposed Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers are substantially equivalent to the predicate Sony Video Graphic Printer UP-850.

Side-by-Side Comparison of Sony UP-X898MD / UP-D898MD Graphic Printers with Sony Video Graphic Printer UP-850

Product Characteristics	Sony Electronics Inc. Sony UP-X898MD / UP-D898MD Graphic Printers	Sony Electronics Inc. Sony Video Graphic Printer UP-850
Regulatory Status	**Proposed**	**K890826**
Product Code	**LMC**	**KQM**
Indications for Use	The Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers are compact, medical grade black and white digital printers. The Sony UP-D898MD (Digital) Graphic Printer accepts only digital signal inputs. The Sony UP-X898MD (Hybrid) Graphic Printer can accept both analog and digital signal inputs. Both models are designed to be integrated into digital radiology imaging systems such as mobile c-arm, ultrasound, cardiac catheterization laboratory and other compatible medical imaging systems and produce hard copy prints of still images captured by these systems for the patient record or for referrals.	The Sony Video Printers UP Series is a general purpose device and is intended for use as an accessory for a wide range of electronic medical diagnostic equipment to provide hard copy images. This equipment includes ultrasound and radiological imaging systems and surgical camera systems as well as any other systems that generate the specified video signal output.
	Features	
Printing Method	Direct thermal printing	Direct thermal printing
High Resolution	325 dpi	325 dpi
Gradations	256 levels	128 levels
Picture Elements	UP-X898MD: • Digital: 4096 x 1280 dots • Video NTSC: 720 x 504 dots • Video PAL: 720 x 604 dots UP-D898MD: • Digital: 4096 x 1280 dots	NORM: 472 lines x 700 dots (EIA), 560 lines x 700 dots (CCIR) WIDE1: 490 lines x 736 dots (EIA), 582 lines x 736 dots (CCIR) WIDE2: 508 lines x 768 dots (EIA), 608 lines x 768 dots (CCIR)
Picture Area	UP-X898MD: • Digital: 320 x 100 mm (12 5/8 x 3 7/8 inch) (Max) • STD Video NTSC: 94 x 73 mm • Video PAL: 94 x 71 mm (WIDE1) • SIDE Video-NTSC: 124 x 96 mm, Video-PAL: 127 x 96 mm (WIDE1) UP-D898MD: • 320 x 100 mm (12 5/8 x 4 inch)	NORM: 70 x 91 mm (2 2/4 x 3 37/64 inch) (EIA and CCIR) WIDE1: 73 x 96 mm (2 7/8 x 3 25/32) (EIA and CCIR) WIDE2: 75 x 100mm (2 61/64 x 3 15/16 inch) (EIA and CCIR)
Paper Size	110mm (4 3/8 inch)	110mm (4 3/8 inch)
Picture Memory	UP-X898MD: • Digital: 4096 x 1280 x 8 bits • Video: 10 frame memories (850 k x 8 bits per frame)	

Product Characteristics	Sony Electronics Inc. Sony UP-X898MD / UP-D898MD Graphic Printers	Sony Electronics Inc. Sony Video Graphic Printer UP-850
Regulatory Status	**Proposed**	**K890826**
Product Code	**LMC**	**KQM**
	UP-D898MD: • Digital: 4,096 x 1,280 x 8 (bit)	
Interface	UP-X898MD: • USB connector (Type A) • USB connector (Type A) lamp • USB connector (Type B) • Input connector: VIDEO INPUT (BNC type) NTSC or PAL composite video signals, Vp-p, 75 Ω (NTSC or PAL automatically discriminated) • Output connector: VIDEO OUT (BNC type) Loop-through • REMOTE Commander: stereo mini jack UP-D898MD: • USB connector	• Input connector: VIDEO INPUT (BNC type) EIA or CCIR composite video signals, 1.0 Vp-p, 75Ω /high-impedance • Output connector: MONITOR OUT (BNC type), EIA or CCIR, Composite video signals, 1.0 Vp-p, 75 Ω, loop-through/ D/A output changeover switch method • DIP Switches • REMOTE Commander: stereo mini jack
Power Requirements	AC 100 V to 240 V, 50/60Hz	AC 100 V to 240 V, 50/60Hz
Weight	5lb 8oz (2.5 kg)	8lb 10oz (3.9 kg)
Digital Video Input	Yes (UP-D898MD and UP-X898MD)	No
Analog Video Input	Yes (UP-X898MD only)	Yes
Multi-picture Mode	Yes	No
Printing Speed	UP-X898MD: • Approx. 1.9 seconds/image (at standard setting) • Normal speed mode: Approx. 3.3 seconds/image (at standard setting) UP-D898MD: • Approx. 1.9 seconds/image (960 x 1,280 dots) • Normal speed mode: Approx. 3.3 seconds/image (960 x 1,280 dots)	9 seconds per image (at aspect ratio 3:4)
Storage Media	USB Flash drive (UP-X898MD only)	No
Dimensions	6 1/16 (W) x 3 ½ (H) x 9 ½ (D) inches [154 (W) x 88 (H) x 240 (D) mm]	6 1/16 (W) x 6 ½ (H) x 12 43/64 (D) inches [154 (W) x 165 (H) x 322 (D) mm]
LCD Display Panel	Yes	No
LED Backlight	Yes	No
Function Keys	Front Panel	Front Panel
Settings Auto Lock	Yes	No
Contrast Knob	Yes	Yes
Brightness Knob	Yes	Yes
Volume Knob	Yes	No

Product Characteristics	Sony Electronics Inc. Sony UP-X898MD / UP-D898MD Graphic Printers	Sony Electronics Inc. Sony Video Graphic Printer UP-850
Regulatory Status	**Proposed**	**K890826**
Product Code	**LMC**	**KQM**
Menu Lever (Joystick)	Yes	No
Paper Cutter	Yes	Yes
Print Media	Type I: UPP-110S High Quality Printing Paper; Type II: UPP-110HD High Density Printing Paper; and Type V: UPP-110HG High Glossy Printing Paper	Type I: UPP-110S High Quality Printing Paper Type I: UPP-110 High Quality Printing Paper Type II: UPP-110HD High Density Printing Paper
Foot Switch	Optional (FS-24)	Optional (FS-20)
Remote Control	Optional (RM-91)	Optional (RM-81)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 26, 2014

Sony Electronics, Inc.
% Ms. Joanne Bronikowski
Senior Regulatory Project Manager
Aptiv Solutions, an ICON plc company
62 Forest Street, Suite 300
MARLBOROUGH MA 01752

Re: K141454
Trade/Device Name: Sony Digital Printer UP-D898MD/Sony Hybrid Printer UP-X898MD
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: May 30, 2014
Received: June 2, 2014

Dear Ms. Bronikowski:

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" (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.

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,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

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)*
K141454

Device Name
Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers

Indications for Use *(Describe)*
The Sony UP-D898MD (Digital) / UP-X898MD (Hybrid) Graphic Printers are compact, medical grade black and white digital printers. The Sony UP-D898MD (Digital) Graphic Printer accepts only digital signal inputs. The Sony UP-X898MD (Hybrid) Graphic Printer can accept both analog and digital signal inputs. Both models are designed to be integrated into digital radiology imaging systems such as mobile c-arm, ultrasound, cardiac catheterization laboratory and other compatible medical imaging systems and produce hard copy prints of still images captured by these systems for the patient record or for referrals.

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)

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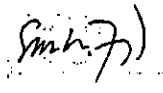
FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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