JUN 2 6 2014 K141346

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510(K) SUMMARY FOR THE SONY ELECTRONICS, INC.
Sony UP-991AD / UP-971AD 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:	Sony UP-991AD / UP-971AD 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 DEVICES

The following devices are legally marketed devices cleared under K882958 as Sony UP Series Video Printers to which equivalence is being claimed:

- UP-701 Video Graphic Printer
- UP-811 Video Graphic Printer
- UP-1000/1100 Color Video Printer
- UP-5000 Color Video Printer

4. DEVICE DESCRIPTION

The UP-991AD and UP-971AD Hybrid Graphic Printers are compact black and white printers designed for use with both analog and digital radiology imaging systems such

as mobile C-arm, ultrasound, cardiac catheterization laboratory and other compatible medical imaging systems. They provide 325 dpi high resolution hard copies of still images captured by the imaging system that can then be used as reference prints for patient record purposes or referrals.[1]

Both the UP-991AD and UP-971AD Hybrid Graphic Printers provide a multi-picture print mode and panoramic print capability. Additionally, the UP-991AD can store images on a connected USB flash drive and print on transparent blue film media, in addition to paper media. Other conveniences offered by the UP-991AD include automatic detection of media type and an integrated media cutter.

5. INDICATIONS FOR USE / INTENDED USE

The Sony UP-991AD / UP-971AD Hybrid Graphic Printers are compact, medical grade black and white printers that can accept both analog and digital signal inputs. They 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 hard copy prints of still images captured by these systems for the patient record or for referrals.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

The proposed UP-991AD and UP-971AD Hybrid Graphic Printers represent a technological upgrade to the predicate Sony UP Series Video Printers. Both the proposed and predicate devices are thermal printers that provide hard copy images captured by connected imaging systems. The proposed UP-991AD and UP-971AD Hybrid Graphic Printers have increased resolution and provide a number of technological features that are not available for the predicate devices – including a multi-picture print mode and panoramic print capability. Additionally, the UP-991AD can store images on a connected USB flash drive and print on transparent blue film media, in addition to paper media. Other conveniences offered by the UP-991AD include automatic detection of media type and an integrated media cutter.

Printer control for the predicate devices is provided by a front panel or keypad. The proposed printers have an LCD display panel with a white LED backlight.

1 The images printed from the UP-991AD and UP971AD are not to be used for diagnosis.

7. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

The safety and effectiveness of the proposed UP-991AD and UP-971AD Hybrid Graphic Printers has 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 60601-1-2:2007-03

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-991AD / UP-971AD Hybrid Graphic Printers are substantially equivalent to the predicate device Sony UP Series Video Printers (subject of K882958). Differences between the proposed and 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-991AD / UP-971AD Hybrid Graphic Printers for its intended use are demonstrated by non-clinical testing. Based on the evidence provided, Sony Electronics believes that the proposed Sony UP-991AD / UP-971AD Hybrid Graphic Printer is substantially equivalent to the predicate Sony UP Series Video Printers.

Side-by-Side Comparison of Sony UP-991AD / UP-971AD Hybrid Graphic Printer with Sony UP Series Video Printers

Product Characteristics	Sony Electronics Inc. Sony UP-991AD / UP-971AD Hybrid Graphic Printer	Sony Medical Electronics Co. Sony UP Series Video Printers (UP-701, UP-811, UP-1000/1100, UP-5000)			
		UP-701	UP-811	UP-1000/1100	UP-5000
Regulatory Status	**Proposed**	**K882958**			
Indications for Use	The Sony UP-991AD / UP-971AD Hybrid Graphic Printers are compact, medical grade black and white printers that can accept both analog and digital signal inputs. They 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 hard copy prints of still images captured by these systems for the patient record or for referrals.	Sony Video Printers are general purpose devices and are intended for use as accessories for a wide range of electronic medical diagnostic equipment to provide hard copy images.			
Product Code	LMC	KQM			
Features					
Printing Method	Direct thermal printing	Direct thermal printing	Direct thermal printing	Sublimation heat transfer printing	Sublimation heat transfer printing
High Resolution	325 dpi	61 dpi	169 dpi	101dpi /132dpi(h/w)	102dpi/118dpi (h/w).
Gradations	8 bits (256 levels) processing	16/32 (black and white)	64 (black and white)	64 levels each (yellow, red, blue)	256 levels each (yellow, magenta, cyan)
Picture Elements	Digital: 7680 x 2560 dots Video NTSC: 720 x 504 dots Video PAL: 720 x 604 dots	235 x 512 dots (NORM), 241 x 512 dots (WIDE):	472 x 602 dots (NORM), 490 x 640 dots (WIDE)	466 x 784 PELS	720 x 468 PELS
Picture Area	DIGITAL: 600 x 200 mm (23 5/8 x 7 7/8 inch) (Max) VIDEO: STD NTSC: 182 x 144 mm PAL: 188 x 140 mm SIDE NTSC: 244 x 184 mm PAL: 244 x 183 mm	NORM 97 x 133mm(3 7/8 x 5 1/4 inches) WIDE 100 x 133(3 7/8 x 5 1/4 inches)	NORM 71 x 90mm(2 3/4 x 3 1/2 inches) WIDE 73 x 96(2 7/8 x 3 3/4 inches)	116.5 x 150mm	116.5 x 155 mm

Product Characteristics	Sony Electronics Inc. Sony UP-991AD / UP-971AD Hybrid Graphic Printer	Sony Medical Electronics Co. Sony UP Series Video Printers (UP-701, UP-811, UP-1000/1100, UP-5000)			
		UP-701	UP-811	UP-1000/1100	UP-5000
Regulatory Status	**Proposed**	**K882958**			
Paper Size	Paper width of 8.25 in. [210 mm]	UPP-110S Paper Roll Width: 4 3/8 inches [110mm] Length: Approx. 6ft 12 3/8 inches [20m]	UPP-110S Paper Roll Width: 4 3/8 inches [110mm] Length: Approx. 6ft 12 3/8 inches [20m]	UPP-1000 MAVIGRAPH Printing Paper – 100 sheets 5 3/8 x 8 3/8 inches [140 x 210 mm]	Color: UPC-5010 – 100 sheets OHP: UPC-5030 – 50 sheets
Picture Memory	Digital: 2816 x 7680 x 8 bits Video: 6 frames (720 x 608 x 8 bits for one frame)	128K x 4 bits	448K x 5 bits	357K x 6bits	1024K x 8bits
Interface	USB terminal (type A) for USB flash drive (X1) (UP-991AD only) Hi-Speed USB (USB 2.0) (x1) VIDEO INPUT: BNC type (X1) NTSC or PAL composite video signals 1.0Vp-p, 75ohm (NTSC/PAL automatically discriminated) VIDEO OUTPUT: BNC type (x1) Loop-through REMOTE: Stereo mini jack (x1)	VIDEO INPUT: BNC type NTSC composite video signals 1.0Vp-p or 5.0 Vp-p, 75ohms/high impedance REMOTE: Stereo mini jack	VIDEO INPUT: BNC type NTSC composite video signals 1.0Vp-p or 5.0 Vp-p, 75ohms/high impedance MON OUT: BNC type NTSC composite video signals 1.0Vp-p. 75 ohms Loop-through/D/A Output Changeover Switch Method REMOTE: Stereo mini jack	VIDEO INPUT: BNC type Composite video signals 1.0 +0.6/-0.3 Vp-p, 75 ohms, negative COMPONENT INPUT: BNC type R/R-Y, G/Y, B/B-Y [R-Y, Y, B-Y Y 1.0+0.6/-0.3 Vp-p R-Y, B-Y, 0.7+0.4/-0.2 Vp-p R,G,B (analog) 0.7+0.4/-0.2 Vp-p TTL (digital RGB) TTL level (positive polarity), 22 kilohms] SIGNAL INPUT: SYNC:BNC type, 4.0+1.3/-3.7 Vp-p (negative polarity) 75 ohms HD,VD:BNC type, 5.0+3.0/-4.0 Vp-p (negative polarity), 5 kilohms MONITOR OUTPUT: MONITOR: BNC type [R,G,B 0.7 +-0.1 Vp-p, 75 ohms	VIDEO INPUT: BNC type NTSC Composite video signals 1.0 Vp-p. 75 ohms, negative COMPONENT INPUT: [R-Y, B-Y, Y 16 pin connector Y: 1.0 Vp-p, 75 ohms R-Y, B-Y: 0.7 Vp-p, 75 ohms R,G,B VIDEO INPUT: BNC type, 0.7 Vp-p, 75 ohms S VIDEO INPUT: (Separate luminance(Y) and Chrominance© signals) Y: 1 Vp-p C: 0.29 Vp-p 75 ohms MONITOR OUTPUT: RGB 25 pin connector R,G,B: 0.7 Vp-p, 75 ohms SYNC: 1 Vp-p (negative polarity), 75 ohms VIDEO (NTSC composite video signal)

Product Characteristics	Sony Electronics Inc. Sony UP-991AD / UP-971AD Hybrid Graphic Printer	Sony Medical Electronics Co. Sony UP Series Video Printers (UP-701, UP-811, UP-1000/1100, UP-5000)			
		UP-701	UP-811	UP-1000/1100	UP-5000
Regulatory Status	**Proposed**	**K882958**			
				SYNC 1.0 +-0.4 Vp-p (negative polarity) 75 ohms	BNC type, 1 Vp-p, 75 ohms, negative CONTROL-1 (Keypad connector) 9 pin CONTROL-2 (Automatic printing connector) Stereo mini jack RS-232C 25 pin
Power Requirements	AC 100 V to 240 V, 50/60 Hz	AC 100 V to 120 V, 50/60 Hz	AC 100 V to 120 V, 50/60 Hz	AC 120 V, 60 Hz	AC 120 V, 50/60 Hz
Weight	15lb 7oz [7.0 kg]	7lb 15oz [3.6 kg]	8.8lb [4.0 kg]	102lb 12oz [46.6 kg]	33lb 1oz [15 .0 kg]
Digital Video Input	N/A	N/A	N/A	N/A	N/A
Analog Video Input	Yes	Yes	Yes	Yes	Yes
Multi-picture Mode	Yes - 2, 4, and 6 (Analog) / 2 and 4 (Digital)	N/A	N/A	Yes - 4	Yes - 4, 9
Panoramic Printing	Yes up to a maximum of 600mm in length	N/A	N/A	N/A	N/A
Printing Speed	Approx. 8 seconds/image (in standard mode)	8.5 seconds/screen	8.8 seconds/screen	Color ribbon : 3 minutes; Black ribbon : 1 minute	1 minute
Storage Media	• USB Flash drive (UP-991AD only)	N/A	N/A	N/A	N/A
Dimensions	12.5 (W) x 5.25 (H) x 10.5 (D) inches (D) [316 (W) x 132.5 (H) x 265 (D) mm]	6 1/8 (W) x 6 ½ (H) x 12 ½ (D) inches [154 (W) x 166 (H) x 318 (D) mm]	6 1/8 (W) x 6 ½ (H) x 12 ½ (D) inches [154 (W) x 165 (H) x 318 (D) mm]	29 3/8 (W) x 12 1/8 (H) x 16 (D) inches [743 (W) x 307 (H) x 405 (D) mm]	16 3/4 (W) x 7 1/2 (H) x 18 3/4 (D) inches [424 (W) x 190 (H) x 474 (D) mm]
LCD Display Panel	Yes	N/A	N/A	N/A	N/A
LED Backlight	Yes	N/A	N/A	N/A	N/A
Function Keys	Front Panel	Front Panel	Front Panel	Operation Panel	Keypad
Settings Auto Lock	Yes	N/A	N/A	N/A	N/A
Contrast Knob	Yes	N/A	Yes	N/A	N/A
Brightness Knob	Yes	N/A	Yes	Yes	N/A
Automatic Media Cutter	Yes (UP-991AD only)	N/A	N/A	N/A	N/A
Automatic Detection of Media Type	Yes (UP-991AD only)	N/A	N/A	N/A	N/A
Print Media	UPT-210BL Blue Thermal Transparent Film (UP-991AD	UPP-110S	UPP-110S	UPP-1000	UPC-5010: Color UPC-5030: OHP

Product Characteristics	Sony Electronics Inc. Sony UP-991AD / UP-971AD Hybrid Graphic Printer	Sony Medical Electronics Co. Sony UP Series Video Printers (UP-701, UP-811, UP-1000/1100, UP-5000)			
		UP-701	UP-811	UP-1000/1100	UP-5000
Regulatory Status	**Proposed**	**K882958**			
	only); UPP-2010HD, UPP-210SE Thermal Print Media				
Ribbon	N/A	N/A	N/A	UPR-1001: Color UPR-1002: Black	
Foot Switch	Optional (FS-24)	N/A	N/A	N/A	N/A
Remote Control	Optional (RM-91)	Optional (RM-81)	Optional (RM-81)	N/A	Yes

N/A = Not applicable

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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: K141346
Trade/Device Name: Sony Hybrid Graphic Printers (UP-971AD and UP-991AD)
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: May 16, 2014
Received: May 22, 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.

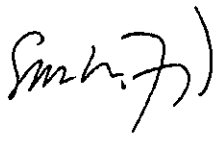
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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)*

K141346

Device Name
Sony Hybrid Graphic Printer UP-971AD
Sony Hybrid Graphic Printer UP-991AD

Indications for Use *(Describe)*

Sony Hybrid Graphic Printers UP-971AD and UP-991AD are compact, medical grade black and white printers that can accept both analog and digital signal inputs. They 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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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