K083522

510(k) Summary
for
Sony UP-DF750 Digital Film Imager
(per 21 CFR 807.92)

JAN - 9 2009

1. APPLICANT / SPONSOR

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

Contact Person: Mr. John Kefalos
Telephone: 201-358-4330

Date Prepared: November 24, 2008

2. DEVICE NAME

Proprietary Name: Sony UP-DF750 Digital Film Imager
Common/Usual Name: Thermal Printer/Imager
Classification Name: Medical Image Hardcopy Device

3. PREDICATE DEVICES

- Agfa Healthcare Corporation, Drystar AXYS, K072680
- Agfa Healthcare Corporation, Drystar 4500M, K012941
- FUJIFILM Medical Systems, USA, Inc., Fuji Medical Dry Laser Imager, Model DRYPIX 7000, K033377
- Eastman Kodak Company, KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory, K033821
- Konica Minolta Medical & Graphic Inc., Dry Laser Imager, DRYPRO Model 793, K042133
- Sony Medical Systems Division, UP-DF500 FilmStation Digital Film Imager, K024188

4. DEVICE DESCRIPTION

The Sony UP-DF750 Digital Film Imager is a device for digitally printing black and white still images with DICOM format. The Sony UP-DF750 Digital Film Imager is connected to a DICOM network and the image from a mammography, CT, MRI, CR, DR or other compatible medical imaging system (modality) is transmitted via the DICOM network. Whenever a DICOM file is received, the Sony UP-DF750 Digital Film Imager will understand the DICOM information and images will be formatted in the memory. Then, this information will be transferred to the Print Engine through an internal interface (I/F). The data will be processed through sharpness, gamma curve and other types of compensation. The Sony UP-DF750 Digital Film Imager is intended to be used to print DICOM images obtained from a medical modality for the purpose of diagnosis.

5. INTENDED USE

The Sony UP-DF750 Digital Film Imager is a thermal printer intended for use in printing medical diagnostic images from mammography systems. The UP-DF750 is a multi-format imager and also is intended for printing high-resolution diagnostic images from CT, MRI, CR, DR and other compatible medical imaging systems. The Sony UP-DF750 is intended for use by medical radiologists or other appropriately trained medical personnel.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Sony UP-DF750 Digital Film Imager has the same overall purpose and function as the predicate devices cited above. All of the systems are intended to print a high-resolution, hard copy of an image generated by a medical imaging system. The printed images can be used for medical diagnostic purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Sony Electronics, Inc.
% Cynthia Sinclair, RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K083522
Trade/Device Name: Sony UP-DF750 Digital Film Imager
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: November 24, 2008
Received: November 26, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083522

Device Name: Sony UP-DF750 Digital Film Imager

Indications for Use:

The Sony UP-DF750 Digital Film Imager is a thermal printer intended for use in printing medical diagnostic images from mammography systems. The UP-DF750 is a multi-format imager and also is intended for printing high-resolution diagnostic images from CT, MRI, CR, DR and other compatible medical imaging systems. The Sony UP-DF750 is intended for use by medical radiologists or other appropriately trained medical personnel.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083522