K092280

510(k) SUMMARY

VIRTUAL IMAGING
A CANON USA Company

Canon

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OCT 16 2009

Date Prepared	July 20, 2009
Summary prepared by:	Chris Duca, Chief Operating Officer
Device Name	Medical Image Hardcopy Device (Printer)
Trade Name	Cypher DICOM Print Solution
Common Name	Printer
Classification	Class: II Product Code: LMC Regulation: 21 CFR 892.2040;
Identification of Predicate Devices and Summary of Substantial Equivalence	Horizon® Series MEDICAL IMAGE HARDCOPY MULTIMEDIA PRINTERS, K060440 and K042232, manufactured by Codonics,
Device Description	CYPHER implements the necessary DICOM services to receive DICOM print jobs and provides an interface for printing the received data on a Windows™ printer. The device is designed for use with the CANON imagePRESS™ C1 Digital Print System. It consists of an Intel® 945GSE Mini-ITX Board in a shielded enclosure. The user interface is implemented on either an attached monitor or via the remote desktop function inherent in Windows XP. Power is supplied via an external UL listed 12 volt power supply.

Intended Use and Indications	This device is intended for high resolution hard copy imaging of digital image source material (DICOM). The hardcopy output includes however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR and Radiation Therapy planning; Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians. Not for mammography use.
Technological Characteristics and Substantial Equivalence	Comparison with the predicate shows the technological characteristics of the Cypher DICOM Print Solution are equal to or better than the predicate device. Both units are DICOM compatible (optional on the predicate) and produce high quality hardcopy printouts in black & white and color.
Performance Testing/Data	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests include: Software Validation and evaluation of hardcopy output. Electrical safety is assured via use of a UL listed power supply.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Virtual Imaging, Inc.
% Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
333 Milford Road
DEERFIELD IL 60015

OCT 16 2009

Re: K092280
Trade/Device Name: Cypher DICOM Print Solution
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: July 21, 2009
Received: July 28, 2009

Dear Mr. Kamm:

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 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,

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): K092280
Device Name: Cypher DICOM Print Solution

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Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (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 K092280