

Section 5 - Revised 3/10/2010:

APR - 5 2010

510(K) Summary (K093790)

Prepared: February 24, 2010

Submitter:

Company Name: SimonDR Inc.
Company Address: 3515 Marmenco Court
Baltimore, Maryland 21230
Contact Person: Jason Simon, President
Official Correspondent: Valerie Lohr, General Manager
Phone Number: 410-636-5555
Fax Number: 410-636-4415

Proposed Device:

Reason For 510(K): New Device
Manufacturer: SimonDR Inc.
Trade Name: SimonDR
Model Number: DRP
Classification Name: 90 MQB SSXI- Solid State X-Ray Imager
FDA 510(k)#: Submission in progress

Predicate Device(s) 1:

Manufacturer: Kodak (Carestream) Lanex Screen/AGFA 1/2 Speed Film
Trade Name: Kodak/Carestream
Model Number: Lanex
Classification Name: Radiographic film/screen system
FDA 510(k)#: N/A

Predicate Device(s) 2:

Manufacturer: Canon Inc.
Trade Name: Canon
Model Number: CXDI-55G
Classification Name: MQB, Solid State X-Ray Imager
FDA 510(k)#: K091345

Description of Device :

The SimonDR Inc. model DRP is used to directly capture and convert conventional projection X-Ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for podiatric radiographic examinations.

The full Device Comparison Table is found in section 12 of this application; however, in terms of Resolution (MTF) and Dynamic Range the comparison with the digital and analog predicate device is found below.

Characteristic	SimonDR Inc. Model DRP	Lanex Detail Screen/Film System Device 1
MTF	4.0 lp/mm 35%	4 -5 lp/mm 35% (see also Section 18)
Dynamic Range	Up to 16 bit capture, display ranging from 8 to 12 bits	Approximately 20 (about 5 bits), depending on film processing

Characteristic	SimonDR Inc. Model DRP	Canon Device 2
MTF	4.0 lp/mm 35%	MTF@2 lp/mm 40%
Dynamic Range	Up to 16 bit capture, display ranging from 8 to 12 bits	(linear A/D: 14 bit) (output data: 12 bit)

Intended Use:

The SimonDR DRP is a digital x-ray Imager intended for physicians, or technologists operating under the supervision of a physician, to use for podiatric x-ray instead of using a film based system.

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 _____

Prescription Use XX

OR Over-The-Counter Use _____

510(k) Summary Statement

I certify that in my capacity as President of Simon DR, Inc, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent, The information I agree to make available will be a duplicate of the premarket notification including any adverse safety and effectiveness information, but excluding

all patient identification, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Signed:

A handwritten signature in black ink, appearing to read 'Jason Simon', with a long horizontal flourish extending to the right.

Jason Simon

President

Date: 2/24/2010



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

Ms. Valerie Lohr
General Manager
SimonDR, Inc.
3515 Marmenco Court
BALTIMORE MD 21230

Re: K093790
Trade/Device Name: SimonDR DRP
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 11, 2010
Received: March 15, 2010

AUG 23 2013

Dear Ms. Lohr:

This letter corrects our substantially equivalent letter of April 5, 2010.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

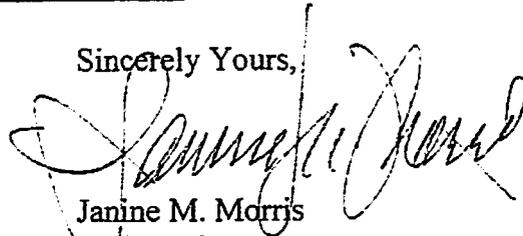
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510K number: Submission in progress K093790

Device Name: SimonDR DRP

Indications For Use: The Models SimonDR DRP Digital X-Ray Imager is a digital x-ray Imager intended for physicians or technologists operating under the guidance of the physician, to use for diagnostic x-ray imaging in podiatric practices instead of using a film based system.



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K093790