510(k) Summary K133106

This 510(k) summary information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: December 12, 2013

JAN 15 2014

1. Company and Correspondent making the submission:

Name – 3D Imaging & Simulations Corp.
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Contact – Jiin Jung / Vice President
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2. Device :

Trade/proprietary name: FireCR Spark
Common Name: Computed Radiography Scanner
Classification Name: Stationary x-ray system

3. Predicate Device :

Manufacturer: 3D Imaging & Simulations Corp.
Device: FireCR
510(k) Number: K102619 (Decision Date – Mar. 1. 2011)

4. Classifications Names & Citations :

21CFR 892.1680, MQB - Stationary x-ray system, Class 2

5. Description :

5.1 General

The FireCR Spark is Computed Radiography System which produces the X-ray diagnostic image in digital format instead of using traditional screens and film. This device utilizes reusable X-ray storage phosphor plate (IP) that is sensitive to X-ray and stores latent image when it is exposed to X-ray. After X-ray exposure to the X-ray storage phosphor plate, X-ray storage phosphor plate is scanned by means of laser in the device. Latent image in the X-ray storage phosphor plate is released in a form of light by laser scanning. Then the light is collect and converted into a form of digital image. The signal processing is made to the digital image data such as the digital filtering, the gain & offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, then stored locally, sent to an archive, printed or sent to PACS system. After acquisition of latent image from the X-ray storage phosphor plate, it is erased thoroughly to be reused.

5.2 Main Features

Modern Scanning Mechanism
FireCR Spark adopts an updated scanning mechanism constructed in a compact and rigid structure.
High Throughput: Its unique scanning mechanism enables to improve the efficiency and high throughput.
Scanning Resolution: User selectable resolution of 100μm and 200μm allows user to make diagnosis on variable purposes.
Detector
High sensitivity photomultiplier tube supplied in the FireCR Spark delivers high gain, wide dynamic range and high speed response for radiographic imaging.
Acquisition and Diagnostic Software: QuantorMed Plus Acquisition and Diagnostic Software's accurate and rapid data processing make the scanner powerful.

5.3 Product features

- Photomultiplier Tube (PMT)
- 35cm x 43cm, 24cm x 30cm, 18cm x 24cm imaging area.
- Wide dynamic range with 16-bit digitization

- Image process parameters are selectable according to the body part to make best images for diagnosis
- DICOM3.0 standard compliance
- User Selectable Scanning Resolution : 100μm and 200μm

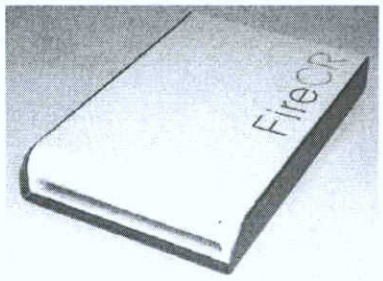
6. Indications for use :

This device is a Computed Radiography System and intended for use in producing digital X-Ray images for general radiography purposes. It comprises of scanner, cassette with reusable phosphor storage plate (IP) and workstation software. It scans X-Ray exposed image plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing. This device is intended to be operated in a radiological environment by qualified staff. This device is not intended for the acquisition of mammographic image data.

7. Comparison with predicate device :

3D Imaging & Simulations Corp. believes that the FireCR Spark is substantially equivalent to FireCR.

		FireCR 3D Imaging & Simulations Corp.	FireCR Spark 3D Imaging & Simulations Corp.
510(k) number		K102619	K133106
Intended Use		The FireCR imaging system is indicated for capturing, digitization and processing of general radiography images stored in imaging plate recording media.	The FireCR Spark imaging system is indicated for capturing, digitization and processing of general radiography images stored in imaging plate recording media.
Physical Characteristics	Overall Dimensions	Reader 464 x 703 x 117mm	Reader 445 x 795 x 80 mm
	Imaging Area	14" x 17" (35cm x 43cm) 10" x 12" (25cm x 30cm)	35cm x 43cm SAME 24cm x 30cm (SLIGHT DIFFERENCE) 18cm x 24cm (NEW SIZE)
	Effective Pixel Pitch	100μm, 200μm	100μm, 200μm
	Spatial Resolution	3.7lp/mm @ 100um	3.7lp/mm @ 100um
	Image Matrix (Pixel)	35cm x 43cm 3500 x 4300 @ 100um 1750 x 2150 @ 200um 25cm x 30cm 2500 x 3000 @ 100um 1250 x 1500 @ 200um	35cm x 43cm SAME: 3500 x 4300 @ 100um SAME 1750 x 2150 @ 200um SAME 24cm x 30cm (SLIGHT DIFFERENCE): 2400x3000 @ 100um (SLIGHT DIFFERENCE) 1200 x 1500 @ 200um (SLIGHT DIFFERENCE) 18cm x 24cm (NEW SIZE): 1800 x 2400 @ 100um 900 x 1200@ 200um
	Weight	30kg	19.5kg
	Imaging Device	High Sensitivity Photo Multiplier Tube (s-PMT)	High Sensitivity Photo Multiplier Tube (s-PMT)

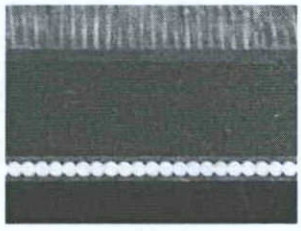
		FireCR 3D Imaging & Simulations Corp.	FireCR Spark 3D Imaging & Simulations Corp.
Photo			
Operational Characteristics	Operating Condition	Temperature :0-40°C Humidity: 15%-95% RH	Temperature :0-40°C Humidity: 15%-95% RH
	Power Requirements	100-250VAC +/- 10%, 50/60Hz	100-250VAC +/- 10%, 50/60Hz
	Methods of Exposure	Register Patient → X-ray Exposure	Register Patient → X-ray Exposure
	X-ray Absorber	Imaging plate	Imaging plate
Functional Characteristics	Output Data	Dicom3.0 Compatible	Dicom3.0 Compatible
	DQE	23.5% @ 0.5 lp/mm	25% @ 0.5 lp/mm
	MTF	79% @ 0.5 lp/mm	80% @ 0.5 lp/mm
	Defect Compensation	By Calibration	By Calibration
	Dynamic Range	16bit	16 bit
	Image Processing	Image processing parameter is selectable by body part	Image processing parameter is selectable by body part
DICOM Compatibility		DICOM 3.0 Compliant	DICOM 3.0 Compliant
Standards		IEC 60601-1; IEC 60601-1-2 IEC 62220-1	SAME

The FireCR Spark's imaging principle, physical characteristics, target population and intended use are the same as those of FireCR. However, the differences in the design are follows:
- The technical specification (including DQE, MTF), mechanical structure and physical appearance of the FireCR Spark is a little different from the FireCR. - The testing of the FireCR Spark demonstrates that the performance is substantially equivalent to the predicate devices cited above.
In clinical considerations, - The rating was considered equivalent by radiologists.
- As a result of Clinical Study, FireCR Spark is considered that Image quality is equivalent to the Predicate Device.

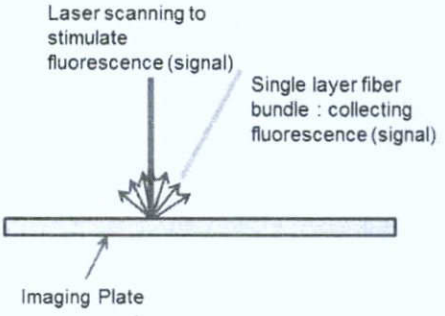
Summary of comparison:
The FireCR Spark described in this 510(k) has the same intended use and similar technical characteristics to the FireCR. The similarities and differences between these systems are described in the table shown above.

The similarities are as follows:
Intended use with FireCR; Capturing image, Image Processing, and DICOM compatible features with FireCR X-ray exposing technique with FireCR; Effective Pixel Pitch with FireCR; Spatial resolution with FireCR; X-ray absorber material with FireCR; Image making process with FireCR; Energy Sources, Source to skin distance with FireCR; Workstation and operating system with FireCR

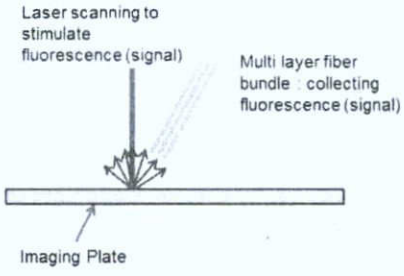
Differences are as follows:
(1) Difference in Mechanical Structure and Physical Appearance (Now the structure is more modular)
Mechanical structure and physical appearance of FireCR Spark is different from those of FireCR.
(2) Difference in DQE and MTF: FireCR Spark shows slightly better DQE and MTF compared to the FireCR.
This is due to the uses of a multi layer fiber bundle.



Single Layer Fiber Bundle



Multi Layer Fiber Bundle



(3) A new panel size is now available, allowing the user greater imaging flexibility (see table above).
In summary, The FireCR Spark does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

8. Safety, EMC, Biocompatibility and Performance Data :
Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).
Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed. All test results were satisfactory.

9. Conclusions :
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification 3D Imaging & Simulations Corp. concludes that the Computed Radiography Reader System (FireCR Spark) is safe and effective and substantially equivalent to predicate device as described herein. These modifications pose no risk to safety and effectiveness because they enhance reliability (modular construction) and they provide slightly better performance characteristics (multi layer fiber bundle) rendering the modifications substantially equivalent to our predicate device. There is also an added imaging plate size which gives the user a greater choice in their imaging needs (18cm x 24cm NEW SIZE, 1800 x 2400 @ 100um and 900 x 1200@ 200um.

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

January 15, 2014

3DISC Americas
% Daniel Kamm, P.E.
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K133106
Trade/Device Name: Fire CR Spark
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 12, 2013
Received: December 16, 2013

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. 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 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. 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,

for

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

Enclosure

Indications for Use

510(k) Number (if known): K133106

Device Name: Computed Radiography Scanner / FireCR Spark

Indications for Use:

This device is a Computed Radiography System and intended for use in producing digital X-Ray images for general radiography purposes. It comprises of scanner, cassette with reusable phosphor storage plate (IP) and workstation software. It scans X-Ray exposed image plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing. This device is intended to be operated in a radiological environment by qualified staff.

This device is not intended for the acquisition of mammographic image data.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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