Carestream Health, Inc.
% Duane Gutowski
Manger Regulatory Affairs, Clearance and Surveillance
150 Verona Street
ROCHESTER NY 14608

February 18, 2020

Re: K192894
Trade/Device Name: Vita Flex CR System with LLI
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: January 14, 2020
Received: January 21, 2020

Dear Duane Gutowski:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192894

Device Name
Vita Flex CR System with LLI

Indications for Use *(Describe)*
The Vita Flex CR System is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images. The LLI is indicated for Long Length Imaging examinations of long areas of anatomy such as the leg and spine.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Carestream

"510(k) Summary"

K192894

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, NY, 14608
510(k) Owner Phone:	585-627-8760
510(k) Owner Fax:	585-323-7643
Contact Person & Info:	Duane Gutowski Regulatory Affairs Manager duane.gutowski@carestream.com 585-627-8760
Date Summary Prepared:	January 14, 2020
Device Trade Name:	Vita Flex CR System with LLI Manufactured by: Carestream Health, Inc. Systems
Device Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	Stationary x-ray system
Device Class:	2
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Device:	Point of care including LLI Manufactured by: Carestream Health, Inc. Systems 510(k) No.: K073670 (01/25/2008)
Predicate Device Class:	2
Predicate Device Code:	MQB
Regulation Number:	21 CFR 892.1680

Device Description:

The Vita Flex CR System with LLI is a Computer Radiography (CR) acquisition scanner, which includes mechanical and software interface to the LLI cassette. The device is constructed from a Man Machine Interface panel, a CR scanner and infrastructure, which enables connection to external applications, i.e. to import command messages, to export images and provide status messages. The LLI is a CR cassette, which is used for Long Length Imaging X Ray examinations of long areas of anatomy.

The Vita Flex CR system with LLI accepts an x-ray cassette with a screen. An X-ray cassette is a light-resistant container that protects the screen from exposure to daylight, and allows the passage of X-rays through the front cover on to the phosphor layer of the screen. When stroked by radiation the intensifying screen fluoresces emitting a light that creates the image.

Our Vita Flex CR system take a cassette as an input and it extracts an exposed screen and scans in the image off the screen. The image is stored on the computer system attached to the Vita Flex CR system. Once the scan is complete the screen data is erased and the screen is placed back inside the cassette to be used again by the customer.

When a cassette is properly inserted into the scanner, the scanner will lock the cassette in place. Once locked into place the cassette door can be opened to allow the scanner to feed the screen into the unit.

The operation of the scanning of the LLI cassette and screen will be done exactly as the predicate. Since the size of a long length imaging screen and cassette is large, the operation consists of 2 scans – scanning one half of the image, then turning the cassette around and scanning the second half of the image.

The modified (subject) device is the previously cleared Point of care including LLI CR system which has been modified as follows:

- The working environment of our customers was taken into account and components were selected to improve the conditions under which the system will operate.

- The physical size dimensions have changed slightly as a result of an external appearance design refresh.

- The power module which was internal to the device is now external. Additionally, the power input for the predicate device had three separate power input profiles based on the model. The modified device uses one power input source.

- The laser module in the cleared device is reaching end of life and the replacement chosen has no impact to the functionality of the unit. The modified device has a slightly higher red light wave length, and a slight increase of output power. The negligible difference in the wave length and power output have no impact to the safety or effectiveness of the product.

- The screen erase module in the cleared unit is reaching end of life. The modified device uses a monochromatic red LED light source with an aluminum radiator heatsink. The red LED functions more stable over a longer period of time reducing downtime and maintenance effort. The change to LED light source has no impact to the safety or effectiveness of the product.

Both the modified system and the previously cleared Point of Care including LLI CR system provided the optional console application software, Carestream Image Suite Software. Carestream Image Suite software was chosen for the modified device because it is a software platform that is common across Carestream products. Carestream Image Suite is a FDA cleared device, 510(k) number K100094, decision date on 03/11/2010. The optional Image Suite Software has no impact to the safety or effectiveness of the product.

Predicate Device Description:

The Point of care including LLI is a Computer Radiography (CR) acquisition scanner, which includes mechanical and software interface to the LLI cassette. The device is constructed from a Man Machine Interface panel, a CR scanner and infrastructure, which enables connection to external applications, i.e. to import command messages, to export images and provide status messages. The LLI is a CR cassette, which is used for Long Length Imaging X Ray examinations of long areas of anatomy.

Predicate Indications for Use / Intended Use:

The Point of care is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images. The LLI is indicated for Long Length Imaging examinations of long areas of anatomy such as the leg and spine.

Indications for Use / Intended Use:

The Indications for Use for the device, as described in its labeling, are:
"The Vita Flex CR System is intended for digital radiography using a phosphor storage screen for standard radiographic diagnostic images. The LLI is indicated for Long Length Imaging examinations of long areas of anatomy such as the leg and spine."

The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The Long Length Imaging software component provides the ability to perform operations related to image manipulation and enhancement of medical images.

The Indications for Use for the subject device is the identical to that of the predicate device and the intended use remains unchanged.

Substantial Equivalence:

With the information provided within this submission, we have compared the modified device, Vita Flex CR System with LLI, and the cleared device, Point of Care including LLI, and determined there is no impact to the intended use of the device, no impact to the safety

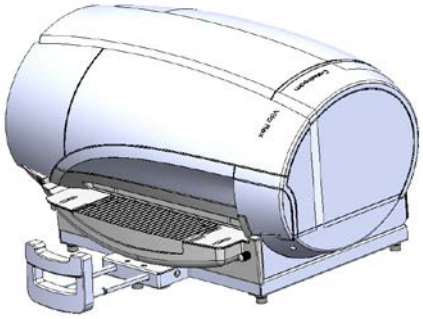
and effectiveness of the system, nor did we alter the fundamental scientific technology of the device.

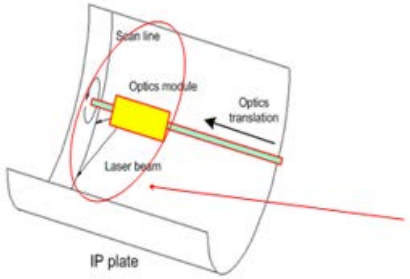
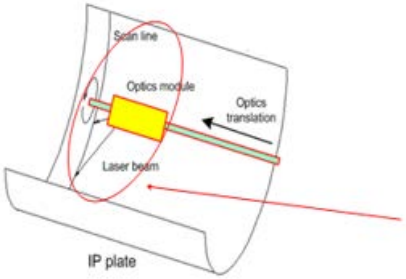
In accordance with FDA Final Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued July 28, 2014, the critical decision points outlined in the proposed 510(k) Decision-Making Flowchart in Appendix A have been considered. The proposed predicate device, Point of care including LLI, has been found substantially equivalent by FDA through the 510(k) process (K073670) and is legally marketed. The Indications for Use for the subject device are identical to the predicate indications and can therefore be considered for substantial equivalence.

A comparison of the modified device Vita Flex CR System with LLI, and the Point of Care including LLI (K073670) is provided in ***Table 1*** below:

Risk assessment of the modifications to the Vita Flex CR System with LLI described in this submission has not identified any new unmitigated risks for the system. Testing to recognized prevailing consensus standards and bench testing have indicated equivalent safety and performance of the modified device. We believe that the modifications to the Vita Flex CR system with LLI do not raise new issues of safety and effectiveness and therefore support a substantial equivalence determination.

Table 1

1. Product Modification Comparison						
Model Type：	Point of Care Including LLI (cleared device)			Vita Flex with LLI (modified device)		
	POC120	POC140	POC260	Vita Flex 30PPH with LLI	Vita Flex 45PPH with LLI	Vita Flex 60PPH with LLI
Product classification:	Medical device class II			Medical device class II		
Product safety classification:	CLASS 1 LASER PRODUCT, and IEC/EN 60825-1. CLASS 1 EQUIPMENT			CLASS 1 LASER PRODUCT, and IEC/EN 60825-1. CLASS 1 EQUIPMENT		
Product Picture:						
Working environment:	Ambient temperature: +10 to + 40°C Relative humidity: 30 - 70%			Ambient temperature: +5 to + 45°C Relative humidity: 25 - 81% Atmospheric pressure: 700 - 1060 hPa		
Physical Size:	658mm x 735mm x 358mm with 45KG Weight			668mm x 675mm x 385mm with 30KG Weight		

Power input:	90～250VAC, 50/60Hz,UPS-online 700VA	90～250VAC, 50/60Hz,UPS-online 700VA	110～250VAC, 50/60Hz,2.5A	100～240VAC, 50/60Hz,1.5A
Power Module	Internal AC/DC converter			External AC/DC converter
Cassette Loading	Manual loading			Manual loading
Screen Access	Autofeed by Driving Roller in Screen Transportation unit			Autofeed by Driving Roller in Screen Transportation Unit
Imaging Module	Laser Platen Scanning: Vertical Direction - Fast Scan: Laser Beam Line Horizontal Direction - Slow Scan: Linear Motor Moving			Laser Platen Scanning: Vertical Direction - Fast Scan: Laser Beam Line Horizontal Direction - Slow Scan: Linear Motor Moving
				
Laser Beam Wave Length：	Red Light Wave Length: 655±10 nm			Red Light Wave Length: 660 ± 7nm
Laser output power(mW)：	22~25			30±2
Laser Level：	Class 3B			Class 3B

Screen Erase Module		Achromatic Light Eraser Fluorescent Lamps Light Source Heatsink: N/A			Monochromatic Light Eraser Red LED Light Source Heatsink: Aluminum Radiator		
Console Connector:		USB 2.0			USB 2.0		
Software Development Kit		Ultra Lite SDK			Ultra Lite SDK		
Long Length Imaging Software		CR Long-Length Imaging System (K021829)			DR Long Length Imaging Software (K130567)		
DICOM:		3.0			3.0		
Image Pixel Depth(Bit):		12			12		
Phosphor screen and cassette specification:	14″ x 17″(Standard configuration)	Supported			Supported		
	10″ x 12″	Supported			Supported		
	8″x 10″	Supported			Supported		
	24 x 30cm	Supported			Supported		
	14″ x 14″	Supported			Supported		
	14″x 33″(LLI)	Supported			Supported		
	10″x 10″(Dental Vet)	Not Supported			Supported		
	15 x 30cm(Dental Panoramic) HR	Supported			Supported		
	9.5" x9.5"	Not Supported	Not Supported	Supported	Not Supported		
Throughput tolerance ±5% (PPH):	14″ x 17″(Standard configuration)	21	40	60	30	45	60
Max Spatial Resolution (LP/mm):	14″ x 33″(LLI)	2.5	2.5	2.5	2.5		
	8″x 10″	4.2	4.2	4.2	4.2		
	10″ x 12″	3.5	3.5	4.2	4.2		
	14″ x 14″	4.2	4.2	4.2	4.2		
	14″ x 17″	4.2	4.2	4.2	4.2		

	24 x 30cm	3.5	3.5	4.2	4.2
	10″x 10″(Dental Vet)	Not Supported			4.2
	15 x 30cm(Dental Panoramic)	4.2	4.2	4.2	4.2
	9.5" x 9.5"	Not Supported	Not Supported	4.2	Not Supported
Min Pixel Pitch(um)：	14″ x 33″(LLI)	173	173	160	160
	8″x 10″	100	100	86	86
	10″ x 12″	125	125	86	86
	14″ x 14″	86	86	86	86
	14″ x 17″	86	86	86	86
	24 x 30cm	125	125	86	86
	10″x 10″(Dental Vet)	Not Supported			86
	15 x 30cm(Dental Panoramic)	100	100	86	86
	9.5" x 9.5"	Not Supported	Not Supported	86	Not Supported
Safety Standard		IEC60601-1			IEC60601-1
EMC Standard		IEC60601-1-2			IEC60601-1-2

Discussion of Testing

The modified Vita Flex CR System with LLI was evaluated by an OSHA approved, nationally recognized test lab, to verify conformance to the following standards:

- IEC 60825-1 Safety of Laser Products - Part 1: Equipment Classification and requirements.
- IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - requirements and tests.

The reports on these IEC standards testing confirm that the modified device meets the international/USA standards on laser safety, medical equipment safety and electromagnetic compliance. Bench testing was performed on the modified device and the results indicate that the Vita Flex CR System with LLI meet or exceed all the requirements in comparison with the predicate device. Given the differences from the predicate device, clinical testing is not necessary for the subject device. Bench testing alone is sufficient to demonstrate substantial equivalence.

Conclusion

The performance characteristics and operation / usability of the modified Vita Flex CR System with LLI were evaluated in non-clinical (bench) testing. These studies have demonstrated the intended workflow, related performance, overall function, verification and validation of requirements for intended use, and reliability of the system software requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.