First Source, Inc.
℅ Ms. Susan Ryan-Kron
Quality & Regulatory Manager
3495 Winton Place, Bldg. E, Ste 1
ROCHESTER NY 14623

March 24, 2021

Re: K203703
Trade/Device Name: I-Q View
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, IZL, LLZ
Dated: February 5, 2021
Received: February 8, 2021

Dear Ms. Ryan-Kron:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203703

Device Name
I-Q View

Indications for Use *(Describe)*
This software is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams.
The product is not intended for mammographic applications.

This software is not meant for mammography, fluoroscopy, or angiography.

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.

510 (k) Summary I-Q View (K203703)

Company Name:	First Source, Inc.
Address:	3495 Winton Place Bldg E, Ste 1 Rochester, NY 14623
Telephone No:	585.272.1690
Registration No.:	3004063527
Contact person:	Susan Ryan-Kron
Date Prepared:	February 5, 2021
Trade/Device Name:	I-Q View
Classification Name:	Stationary X-ray System
DR Regulation No.:	21 CFR 892.1680
Regulatory Name:	Stationary x-ray system
Classification Panel:	Radiology
Regulation Class:	Class II
Product Code:	MQB, IZL, LLZ

Predicate:
K number: K193644
Company Name: LiverMoreTech, Inc.
Trade/Device Name: E-COM DR-2000 DR
DR Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB

Device description:
The I-Q View is a software package to be used with FDA cleared solid-state imaging receptors. It functions as a diagnostic x-ray image acquisition platform and allows these images to be transferred to hard copy, softcopy, and archive devices via DICOM protocol. The flat panel detector is not part of this submission. In the I-Q View software, the Digital Radiography Operator Console (DROC) software allows the following functions:

1. Add new patients to the system; enter information about the patient and physician that will be associated with the digital radiographic images.
2. Edit existing patient information.
3. Emergency registration and edit Emergency settings.

4. Pick from a selection of procedures, which defines the series of images to be acquired.
5. Adjust technique settings before capturing the x-ray image.
6. Preview the image, accept or reject the image entering comments or rejection reasons to the image. Accepted images will be sent to the selected output destinations.
7. Save an incomplete procedure, for which the rest of the exposures will be made at a later time.
8. Close a procedure when all images have been captured.
9. Review History images, resend and reprint images.
10. Re-exam a completed patient.
11. Protect patient records from being deleted by the system.
12. Delete an examined Study with all images being captured.
13. Edit User accounts.
14. Check statistical information.
15. Image QC.
16. Image stitching.
17. Provides electronic transfer of medical image data between medical devices.

Indications for Use (intended use):

This software is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams. The product is not intended for mammographic applications.

This software is not meant for mammography, fluoroscopy, or angiography.

Technological Characteristics:

The I-Q View has the same technological characteristics (e.g. design) as the predicate software. Specifications are essentially the same or similar and there is no impact to the safety nor effectiveness of the diagnostic image quality as a result of this I-Q View software.

Comparison Table:

A comparison chart provides the similarities and differences of technical features of the predicate software and the software for this submission.

Characteristics	**Predicate: LiverMoreTech E-COM DR-2000 (K193644)**	**I-Q View This submission**
Indications for Use	Intended for digital image capture use in general radiographic examinations, wherever convention screen-film systems may be used, excluding	This software is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in

	fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams. This software is not meant for mammography, fluoroscopy, or angiography.
Platform	Windows 10	Windows 10
Compatible solid-state receptors	Toshiba FDX4343R Detector **(K130883)** Toshiba FDX3543RP Detector **(K130883)** Toshiba FDX3543RPW Detector **(K171353)** Toshiba FDX2530RPW Detector **(K162687)** Toshiba FDX4343RPW Detector **(K162687)** Thales Pixium RAD 4143 Detector **(K133139)** Thales Pixium RAD 4343 Detector **(K133139)** Thales Pixium RAD 3543 Detector **(K141440)** Thales Pixium RAD 3543EZ Detector **(K141440)** Thales Pixium RAD 2430EZ Detector **(K141440)** Thales Pixium RAD 3543DR Detector **(K191813)** Varian PaxScan 4336R Detector **(K172007)** Varian PaxScan 4343R Detector **(K172007)** Varian PaxScan 4336X Detector **(K172007)** Varian PaxScan 4336W Detector **(K172007)**	Toshiba FDX4343R Detector **(K130883)** Toshiba FDX3543RP Detector **(K130883)** Toshiba FDX3543RPW Detector **(K171353)** Toshiba FDX2530RPW Detector **(K162687)** Toshiba FDX4343RPW Detector **(K162687)** Thales Pixium RAD 4143 Detector **(K133139)** Thales Pixium RAD 4343 Detector **(K133139)** Thales Pixium RAD 3543 Detector **(K141440)** Thales Pixium RAD 3543EZ Detector **(K141440)** Thales Pixium RAD 2430EZ Detector **(K141440)** Thales Pixium RAD 3543DR Detector **(K191813)** Varian PaxScan 4336R Detector **(K172007)** Varian PaxScan 4343R Detector **(K172007)** Varian PaxScan 4336X Detector **(K172007)** Varian PaxScan 4336W Detector **(K172007)** Careray - 1500Cw **(K150929)** DRTech - ExprimerEVS2430 **(K171137)**, EVS3643 **(K162552)**, EVS4343W **(K193017)**, EVS4343A **(K192400)** iRay - Mars 1417V **(K161730)**, 1717V **(K201043)** Konica Minolta - AeroDR 1210HQ **(K130936)**,

		1417HQ/HD **(K151465)**, 1717HQ **(K172793)** LG – DXD 1417 **(K182348)**, 17HK700G **(K180332)** Pixxgen - PIXX1212 **(K182533),** PIXX1417 **(K182533),** PIXX1717 **(K182533)** Thales - Pixium RAD 4143RC/RG **(K131483)**, 4343RC/RG **(K131483)**, Pixium RAD 4343RC-E/RG-E **(K170113),** Pixium RAD 3543DR-X **(K170113)** Varex - XRpad 4336 **(K140551),** 4343F **(K142698)**, XRpad2 3025 **(K161942),** 4336 **(K161966)**
DICOM 3.0 compatibility	Yes	Yes

Bench Testing:

Bench Testing was conducted via verification and validation. Testing was done to demonstrate the intended functions and the relative performance of the I-Q View software. Integration testing was done to verify that the compatible solid-state detectors listed in the Comparison Table above, performed within specification and as intended. Non-clinical test results have confirmed that the software/device performs to specification and that the submitted I-Q View software is as safe and as functionally effective as the predicate software.

Clinical Testing:

The bench testing is significant enough to demonstrate that the I-Q View software is as good as the predicate software. All features and functionality have been tested and all specifications have been met. Therefore, it is our conclusion that clinical testing is not required to show substantial equivalence.

Conclusion:

The First Source, Inc. I-Q View does not introduce any new indications for use, nor does the use of the software result in any new potential hazards. First Source, Inc. considers the I-Q View digital imaging acquisition software to be substantially equivalent with the predicate with respect to safety and effectiveness.