July 3, 2024

First Source Inc.
℅ Daniel Kamm, P.E.
Kamm and Associates
8870 Ravello Ct.
NAPLES, FL 34114

Re: K240009
Trade/Device Name: iQFlex Pro
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: November 15, 2023
Received: June 6, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K240009

Device Name
iQFlex Pro

Indications for Use *(Describe)*

The iQFlex Pro Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest. - Not to be used on bariatric patients, unless imaging body extremities. Not for mammography use.
Not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary K240009

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

## 1) SUBMITTER

First Source Inc.
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Phone: 585.272.1690, Toll Free: 800.349.5980, Fax: 585.272.7678
https://1stsourceimaging.com
Email: rviola@fsimed.com
Contact Person: Ronald Viola
Position: President
Date Prepared: July 3, 2024

## 2) DEVICE

Name of Device: iQFlex Pro
Regulation Name: Mobile X-ray system
Regulation Number: 892.1720
Regulatory Class: II
Product Code: IZL

## 3) PREDICATE DEVICE

MinXray Inc. K182207
Name of Device: MinXray, MODEL TR90BH
Regulation Name: Mobile X-ray system
Regulation Number: 21 CFR 892.1720
Regulatory Class: II
Primary Product Code: IZL
This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

**4) DEVICE DESCRIPTION.** This Mobile X-ray System (Model: iQFlex Pro) consists of a LED display with up and down soft-keys for controlling kVp, an X-ray generator, an X-ray tube assembly, and a collimator. In addition, this unit has preset memory keys to store and select kVp/mAs. The iQFlex Pro can be used with a flat panel detector of choice. The subject device iQFlex Pro is not being provided with digital detectors. This device is a battery-powered mobile X-ray system, designed and manufactured by First Source Inc. Compared with traditional X-ray products, this device has exquisite structure, compact design, light weight and easy operation. The major components of the X-ray main unit include: handle, enclosure, main/sub console board, high-voltage tank, inverter, collimator (beam limiter), and system control software running on the main console board. The system control software is for real-time interaction and control with various circuit modules inside the X-ray generator. The software responds to user operations on the main console board. The user can adjust and control the kVp and mAs parameters, and the software will display the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the inverter, and control the high-voltage tank to generate high-voltage to excite the X-ray tube inside to emit X-rays, control the switch of the collimator

indicator, and monitor the working status of the device, and control the display of the status indicators. The system is for X-ray imaging and diagnosis in medical facilities with mobile or fixed sites. The iQFlex Pro is not intended for mammography. Detectors are recommended but not provided with the iQFlex system. Detectors chosen must have been cleared by FDA have reasonable MTF and DQE values. The iQFlex Pro is not a cybersecurity device, however it has firmware and a USB-C port. The USB-C port is for battery charging only. The iQFlex Pro generator doesn't connect to the Internet, to other medical devices, and the supporting software doesn't offer a protocol for transfer of medical data.

**5) INDICATIONS FOR USE.** The iQFlex Pro Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician for handheld diagnostic imaging of body extremities The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest - Not to be used on bariatric patients, unless imaging body extremities. Not for mammography use. Not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

**6)** The comparison between the overall specifications of predicate device (MinXray TR90BH) and the subject device (iQFlex Pro) is shown in Table 1.

Table 1. Comparison of Technology Characteristics

| **Item** | **Predicate Device** MinXray TR90BH (K182207) | **Subject Device i$^{Q}$Flex Pro** (without digital imaging) |
|---|---|---|
| Intended Use: | The TR90BH is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities. – Not for mammography use. - The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types | The iQFlex Pro Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician for handheld diagnostic imaging of body extremities The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest. - Not to be used on bariatric patients, unless imaging body extremities. Not for mammography use. Not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.<br>SAME INDICATIONS |
| Weight | 7.5 kg | 5.4 kg (11.9 lbs) LIGHTER |
| Size | 219 x 442 x 190 (mm) | 274 x 227 x 186 (mm) SMALLER SIZE |
| Energy Source | Lithium-Ion Rechargeable Battery, 57.6VDC | Lithium-Ion Rechargeable Battery, 14.4Vdc/6700mAh(4S2P) |
| Output | 20mA @ 40 ~ 60kVDC<br>(2kVp steps) 15mA @ 62 ~<br>80kVDC (2kVp steps) 10mA<br>@ 82 ~ 90kVDC (2kVp<br>steps) High Power Mode<br>15mA @ 82 ~ 90kVDC (2kVp steps) | 50kVp ~ 80kVp, 20mA, 0.4mAs ~ 3.2mAs<br>50kVp ~ 80kVp, 15mA, 4mAs ~ 40mAs<br>81kVp ~ 90kVp, 16mA, 0.4mAs ~ 3.2mAs<br>81kVp ~ 90kVp, 10mA, 4mAs ~ 32mAs<br>91kVp ~ 100kVp, 16mA, 0.4mAs ~ 3.2mAs<br>91kVp ~ 100kVp, 10mA, 4mAs ~ 16mAs<br>SLIGHTLY HIGHER CAPABILITY |

| **Item** | **Predicate Device** MinXray TR90BH (K182207) | **Subject Device i$^{Q}$Flex Pro** (without digital imaging) |
|---|---|---|
| User Interface | Up-Down pushbuttons for kVp selections and exposure time selections with LED indicators mAs indicator | Up/Down pushbuttons for kV/exposure time(mAs) selections and LED indicators for selected kVp/exposure time(mAs) SIMILAR |
| Exposure time | 0.01~1.00sec, 0.01sec step High Power Mode 0.01~0.3sec, 0.01sec step | 0.02~4.00sec: 0.02, 0.03, 0.04, 0.05, 0.06, 0.08, 0.10, 0.13, 0.16, 0.20, 0.40, 0.50, 0.63, 0.80, 1.0,1.30, 1.60, 2.00, 2.50, 3.20, 4.00sec (21 steps) SIMILAR |
| Memory Settings | 10 memories | 5 memories |
| HF Generator | High Frequency | High Frequency SAME |
| kW | 1.35kW | 1.6Kw SLIGHTLY HIGHER |
| kV | 40~90kV | 50~100kVp SLIGHTLY HIGHER |
| X-ray Tube | Canon D-0814, 0.8mm, 16degree, kJ | CEI OX/100, 1.0mm, 16degree, 14kJ |
| Collimator | Mikasa BLD34L | FSI Manual Type, Double Slit |
| Photo |  | Front  Back  |

**7) Performance Testing:**

The i$^{Q}$Flex Pro was tested to and conforms to the following standards:
US FDA Radiation Safety Performance Standard, Sec. 21CFR1020.30 Diagnostic x-ray systems and their major components
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized

with relevant US national differences applied FDA RECOGNITION NUMBER 19-49
IEC 60601-1-2:2014/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements FDA RECOGNITION NUMBER 19-36
IEC 60601-1-3 Edition 2.1 2013-04 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment FDA RECOGNITION 12-269
IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability FDA #5-132
60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy FDA RECOGNITION 12-317
Consulted Guidance: IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems FDA RECOGNITION 19-19

**Discussion of Testing**

The performance characteristics and operation / usability of the iQFlex Pro were evaluated in non-clinical (bench) testing. These studies have demonstrated the intended workflow, related performance, overall function, shipping performance, verification and validation of requirements for intended use, and reliability of the system including both software and hardware requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and test results have demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device. The following performance data were provided in support of the substantial equivalence determination:

- **Electrical safety and electromagnetic compatibility (EMC): Electrical safety and EMC testing were conducted on the iQFlex Pro Mobile X-ray System in compliance to IEC 60601-1:2005/AMD1:2012 and IEC 60601-1-2:2014 – Medical electrical equipment Part 1-2, Electromagnetic Compatibility. EMC Testing was performed for both Class A and Class B environments.**
- **Software Verification and Validation Testing**
  Software verification and validation testing was conducted and documentation Has been provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered to present a "moderate" level of concern. This is based on the fact that a malfunction of or latent design flaw in the software component could lead to an erroneous diagnosis, or to a delay in delivery of appropriate medical care that may lead to a minor injury.
- **Management of Cybersecurity**
  There is a USB-C port on the device, but it is used only for battery charging, so no Internet connection possible. This is not a cybersecurity device even though it has firmware and a USB-C port.
- **Image Quality Evaluation**
  Test images of the head, chest, abdomen, and extremities in order to assure that diagnostic quality imaging can be obtained using this generator. The images were evaluated by a Board

Certified Radiologist and were found to be of excellent diagnostic quality.

8) **Clinical Studies:** A limited clinical test was performed to demonstrate that the device could image anatomy other than extremities. A Board Certified Radiologist performed a successful review**.**

9) **CONCLUSION: After analyzing bench and clinical image tests, it is the conclusion of First Source Inc. that the iQFlex Pro Mobile X-ray System is as safe and effective as the predicate device, has the same indications for use, has few technological differences, which are addressed through performance testing and compliance with the standards listed above, thus rendering it substantially equivalent to the predicate device.**