June 13, 2022

First Source Inc.
% Mr. Woo Sung Park
Consultant
MEDMONTS Co., Ltd.
Life officetel 320, 40, 63-ro, Youngdeungpo-gu
Seoul, 07345
REPUBLIC OF KOREA

Re: K221081
Trade/Device Name: iQFlex M, iQFlex MD Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: February 28, 2022
Received: April 27, 2022

Dear Mr. Park:

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,

Laurel Burk, 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)*
K221081

Device Name
iQFlex M/iQFlex MD Mobile X-Ray System

Indications for Use *(Describe)*
The iQFlex M/iQFlex MD Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).
This device is not intended for mammography.

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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005_510(k) Summary K221081

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.

The assigned 510(k) Number:

I. SUBMITTER

First Source Inc.
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Person: Ronald Viola

Position: President

Date Prepared: Feb.28, 2022

II. DEVICE

Name of Device: iQFlex M/iQFlex MD Mobile X-ray System

Regulation Name: Mobile X-ray system

Regulation Number: 892.1720

Regulatory Class: II

Product Code: IZL

III. PREDICATE DEVICE

MinXray HF120/60HPowerPlus™, K040046

Name of Device: Min Xray, MODEL HF120/60H PowerPlus™

Regulation Name: Mobile X-ray system

Regulation Number: 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.

IV. DEVICE DESCRIPTION

This Mobile X-ray System (Model: i^{Q}Flex M/i^{Q}Flex MD) consists of a LED display with up and down soft-keys for controlling kV, an X-ray generator (line-powered transformer), an X-ray tube assembly, and a collimator. A cart or a stand can be used with the i^{Q}Flex MD. In addition, this unit has preset memory keys to store and select kV/mAs, The i^{Q}Flex M/i^{Q}Flex MD is used with a film-cassette or flat-panel detector. The image detectors (a necessary component of a fully-functional diagnostic system) are not part of this submission.

This device is a mains-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, control panel, system control board, high-voltage tank, inverter, collimator (beam limiter), and system control software running on the system control 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 control panel. The user can adjust and control the kV 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 system control board, 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 facilities with mobile or fixing sites.
The i^{Q}Flex M/i^{Q}Flex MD is not intended for mammography.

The device can be used with an X-ray flat panel detector, a computer for receiving and detecting signal results and an image processing software. This mobile X-ray system is designed for handheld or stand-mounted imaging. Model i^{Q}Flex MD can be configured to an optional portable stand that complies with IEC 60601- 1 safety standard. The recommended maximum load that the stand can safely carry is 30kgs to ensure the mechanical stability and effectiveness of the device.

The cybersecurity risks of the i^{Q}Flex M/i^{Q}Flex MD have been addressed to assure that no new or increased cybersecurity risks were introduced as a part of device risk analysis. These risks are defined as sequence of events leading to a hazardous situation, and the controls for these risks were treated and implemented as proposed in the risk analysis (e.g., requirements, verification).

V. INDICATIONS FOR USE

The i^{Q}Flex M/i^{Q}Flex MD Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician forthe purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).
This device is not intended for mammography.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

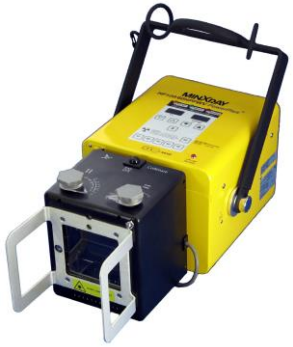
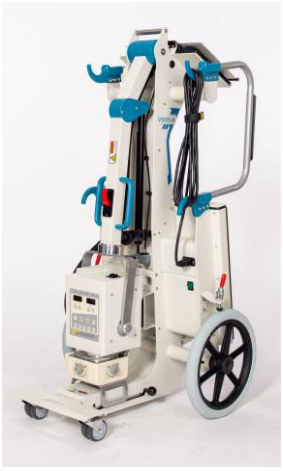
The comparison between the overall specifications of predicate device (MinXray HF120/60HPowerPlus™) and the subject device (i^{Q}Flex M/i^{Q}Flex MD mobile X-ray system) is shown in Table 1.

Table 1 Comparison of Technology Characteristics

Item	**Predicate Device** MinXray HF120/60HPowerPlus™ (K040046)	**Subject Device** i^{Q}Flex M/i^{Q}Flex MD (without digital imaging)
Indications for use	This radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic use.	The i^{Q}Flex M/i^{Q}Flex MD Mobile X-ray System is a medical device intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). The device may be used for handheld diagnostic imaging of body extremities. This device is not intended for mammography.
Weight	17.94 kg	X-ray Generator: 11.0 kg(24.25Ibs) Mobile Cart: 38.1kg (84Ibs)
Size	453*292*224 mm	X-ray Generator - i^{Q}Flex M : 365(L) x 240(W) x 230(H) (mm) - i^{Q}Flex MD : 365(L) x 240(W) x 185(H) (mm) Mobile Cart with X-ray Generator 0.74m x 1.36m(2.41ft. x 4.47ft.); with maximum height positioning: 1m x 2m (3.27ft. x 6.56ft.)
Output	60 mA(0.01-0.1sec), 42 mA (0.11 – 5.0sec) @ 40 - 50 kVDC 50 mA(0.01-0.1sec), 35 mA (0.11 – 5.0sec) @ 52 - 60 kVDC	40kV ~ 60kV, 30mA, 0.4mAs ~ 120mAs 61kV ~ 70kV, 35mA, 0.4mAs ~ 63mAs 61kV ~ 70kV, 30mA, 80mAs ~ 100mAs 71kV ~ 80kV, 30mA, 0.4mAs ~ 50mAs

Item	**Predicate Device** MinXray HF120/60HPowerPlus™ (K040046)	**Subject Device** i^{Q}Flex M/i^{Q}Flex MD (without digital imaging)
	45 mA(0.01-0.1sec), 31.5 mA (0.11 – 5.0sec) @ 62 - 70 kVDC 38 mA(0.01-0.1sec), 26.6 mA (0.11 – 5.0sec) @ 72 - 80 kVDC 33 mA(0.01-0.1sec), 23.1 mA (0.11 – 5.0sec) @ 82 - 90 kVDC 30 mA(0.01-0.1sec), 21 mA (0.11 – 5.0sec) @ 92 - 100 kVDC 20 mA(0.01-0.1sec), 14 mA (0.11 – 5.0sec) @ 102 - 120 kVDC	71kV ~ 80kV, 25mA, 63mAs ~ 80mAs 81kV ~ 90kV, 25mA, 0.4mAs ~ 40mAs 81kV ~ 90kV, 20mA, 50mAs ~ 100mAs 91kV ~ 100kV, 25mA, 0.4mAs ~ 32mAs 91kV ~ 100kV, 20mA, 40mAs ~ 80mAs
Use 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 kV/exposure time(mAs)
Exposure time	(0.01– 0.2sec) in 0.01sec. Step (0.2-0.4sec) in 0.02sec. Step (0.4-1.0sec) in 0.05sec Step (1.0-5.0sec) in 0.1sec Step	0.010~6.000sec. 0.010, 0.013, 0.014, 0.016, 0.017, 0.020, 0.024, 0.025, 0.028, 0.030, 0.033, 0.037, 0.040, 0.043, 0.045, 0.050, 0.052, 0.053, 0.057, 0.064, 0.065, 0.066, 0.071, 0.080, 0.083, 0.091, 0.100, 0.106, 0.114, 0.125, 0.128, 0.133, 0.142, 0.160, 0.166, 0.180, 0.200, 0.210, 0.228, 0.250, 0.252, 0.266, 0.285, 0.315, 0.320, 0.333, 0.371, 0.400, 0.433, 0.457, 0.500, 0.520, 0.533, 0.571, 0.640, 0.650, 0.666, 0.714, 0.800, 0.833, 0.914, 1.000, 1.066,

Item	**Predicate Device** MinXray HF120/60HPowerPlus™ (K040046)	**Subject Device** i^{Q}Flex M/i^{Q}Flex MD (without digital imaging)
		1.142, 1.250, 1.280, 1.333, 1.428, 1.600, 1.666, 1.800, 2.000, 2.100, 2.285, 2.500, 2.520, 2.666, 2.857, 3.150, 3.200, 3.333, 3.428, 4.000, 4.800, 5.000, 6.000 (86 Steps) (0.4~120mAs)
Memory Settings (technique)	5 memories	5 memories
HF Generator	85 kHz	50 kHz
kW	2.4 kW peak -> 3.15	2.5 kW
kVp	40-120 kVp	40-100 kV
X-ray Tube	Superior X-ray Tube Company SXR-130 1.2 mm, 65 kHU	OX/125-1.2(CEI) 1.2mm, 35kHU
Collimator	Advantech -> Collimare	Manual Type, Double Slit
Flat-panel detector	None	PIXXGEN PRUDENT 1212/1417/1717 declared in K211108 DRTECH EVS 4343W/WP, 3643W/WP declared in K193017 VIEWORKS VIVIX-S 1717V declared in K181003 or alternatives U.S. 510(k) cleared
Flat-panel detector	None	PRUDENT 1212 : 140㎛, 2,048 x 2,048 pixels, a-Si/IGZO

Item	**Predicate Device** MinXray HF120/60HPowerPlus™ (K040046)	**Subject Device** i^{Q}Flex M/i^{Q}Flex MD (without digital imaging)
specifications		PRUDENT 1417 : 140㎛, 2,560 x 3,072 pixels, a-Si/IGZO PRUDENT 1717 : 140㎛, 3,072 x 3,072 pixels, a-Si/IGZO EVS 4343W/WP: 140㎛, 3,072 x 3,072 pixels, IGZO EVS 3643W/WP: 140㎛, 2,560 x 3,072 pixels, IGZO VIVIX-S 1717V: 140㎛, 3,072 x 3,072 pixels, a-Si
Photo		 [i^{Q}Flex M]  [i^{Q}Flex MD]

VII. PERFORMANCE DATA

Performance Testing:

The i^{Q}Flex M/i^{Q}Flex MD conforms to the following standards:

ISO 14971:2012	Medical device – application of risk management to medical device
IEC 60601-1:2005/AMD1:2012 EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 / EN60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-3:2008/ A11:2016	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)
IEC 60601-2-54:2015/ EN 60601-2-54:2015	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
IEC 62304:2006/AMD1:2015	Medical device software - Software life-cycle processes
IEC 62366-1:2015/ EN 62366:2008 AMD1: 2015	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Discussion of Testing

The performance characteristics and operation / usability of the i^{Q}Flex M/i^{Q}Flex MD 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 i^{Q}Flex M/i^{Q}Flex MD Mobile X-ray System in compliance to IEC 60601-1-2:2014 – Medical electrical equipment Part 1-2, Electromagnetic Compatibility.
- **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**
  Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued on October 2, 2014) was also followed to consider issues related to cybersecurity in the design and development process of this device.

Clinical Studies

Not applicable. Clinical testing was not deemed to be required to show substantial equivalence. We relied on non-clinical testing and compliance with standards.

VIII. CONCLUSIONS

After analyzing bench tests, it is the conclusion of First Source Inc. that the i^{Q}Flex M/i^{Q}Flex MD 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.