MX Imaging, Inc.
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

May 29, 2020

Re: K201172
Trade/Device Name: CFP-3131, CFP-2222
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: April 29, 2020
Received: May 1, 2020

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. 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)*
K201172

Device Name
CFP-3131, CFP-2222.

Indications for Use *(Describe)*
Intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

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 K201172

MX Imaging Inc.
2894 Columbia Street
Torrance CA 90503-3808 US
310-381-3800

1. **Administrative Information**

Reason for Submission: 510(k) Notification for CFP-3131, CFP-2222.
Submitter: MX Imaging Inc.
Submission contact person:
John Ross john-ross@mximaging.com
Contact telephone: 310-381-3800
Date prepared: May 27, 2020

2. Identification: CFP-3131, CFP-2222.

Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA,

3. Substantially equivalent device:

Trade Name:	CS-series-FP with MX CFP 3131 or MX CFP 2222 Option
Manufacturer:	Omega Medical Imaging, LLC
510(k) #:	K171755
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB, JAA,

4. **Device description:** These CMOS X-ray detectors feature:
The MX Imaging CMOS Flat Panel Detectors are designed for medical x-ray imaging applications. The CMOS panels are real-time x-ray detectors. The Detectors use a state of the art CMOS Imaging sensor that is based on a special pixel architecture enabling the detectors to be used in high sensitivity applications such as x-ray fluoroscopy/pulsed fluoroscopy, as well as applications requiring a large dynamic x-ray range such as radiography serial and radiography applications.

The CMOS Flat Panel Detector is a component, and forms the part of a complete fluoroscopic x-ray system. The CMOS Detector interfaces to the Host X-Ray System through the associated interface connectors on the flat panel. The CMOS Flat Panel Detector is also synchronized to the X-Ray Generator via the interface cables.

The intended use for this device is for Image Intensifier replacement in legacy surgical C-Arm systems.

While we have tested the device with the GE/OEC 9800 and 9900 series of C-Arms it would be appropriate to install them in any standard Image Intensifier based system with the proper mechanical adapter (Weight compensated) and electrical and signal plug adaptations. The system provides a "Plug Compatible" device with the same outputs as the target system. For these reasons no modification of the host system is needed or recommended. In the case of the GE/OEC 9800 the existing input/output connectors connect to the provided detector connectors without modification. Calibration software and instructions are provided with the detector. The existing software and controls all work as before.

5. **Indications for Use:** Intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

6. **Technological characteristics**: Comparison Table

Comparable Properties	K171755 Omega CS-series-FP with MX CFP 3131 or MX CFP 2222 Option radiographic/fluoroscopy system	CFP-3131, CFP-2222. K201172	Comparison Results
Indications for use	Intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging	Intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging	Identical
Digital X-Ray Detectors	MX CFP 3131 and MX CFP 2222	CFP-3131, CFP-2222.	SAME
Detector Sizes	CFP 3131 – 327 x 377 mm CFP2222 – 235 x 292 mm	CFP-3131 – 327 x 377 mm CFP-2222 – 235 x 292 mm	SAME
Pixel Resolutions	CFP-3131 3096x3096 CFP-2222 2170x2170, (1x1 binning)	CFP-3131 3096x3096 CFP-2222 2170x2170, (1x1 binning)	SAME
Power Source	AC Line	AC Line	SAME.
Standards	Same as below	See below	SAME

5. **Non clinical testing:** Testing was performed successfully according to the following standards:

Standard Developing Organization	Standard Designation Number And Date	Title of Standard
ANSI/AAMI	ANSI/AAMI ES60601-1: 2005 +C1:2009 +A2:2020 +A1:3012	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance

Standard Developing Organization	Standard Designation Number And Date	Title of Standard
IEC	60601-1-2:2007	Medical Electrical Equipment Part 12: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements And Tests
Food and Drug Administration	21CFR 1020.30, 1020.31, and 1020.32 Current Version	Meets the applicable requirements of the US FDA Radiation Safety Performance Standard

Non-clinical testing was performed in accordance with the FDA Guidance Document Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, *Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016*. In recognition of possible cybersecurity threats to the software, we consulted this guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff October 2014*. As a result, we updated our own internal standard operating procedures and added cybersecurity precautions to the software users' manuals. Also we have utilized FDA's pediatric guidance, *"Pediatric Information for X-ray Imaging Device Premarket Notifications"* in the preparation of our labeling documentation. Conforms to applicable portions of the US Radiation Safety Performance Standard, conformance with applicable portions of 21 CFR 1020.30, 1020.31, and 1020.32.

6. Clinical testing. Not required for a determination of substantial equivalence.

7. Substantial Equivalence Discussion.

When combined with compatible c-arm combination the CFP 3131 - CFP2222 - performs the same functions using the same technological methods to produce diagnostic fluoroscopic x-ray images. In all material aspects, the Omega and the MX Imaging systems are substantially equivalent to each other.

8. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of MX Imaging LLC that the CFP 3131 - CFP2222 - is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.