February 9, 2018

Omega Medical Imaging, LLC
% Mr. John Newman
Manager of Regulatory and Quality
675 Hickman Circle
SANFORD FL 32771

Re: K171755
Trade/Device Name: CS-series-FP with MX CFP 3131 or MX CFP 2222 Option radiographic/fluoroscopy system
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: January 4, 2018
Received: January 10, 2018

Dear Mr. Newman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171755

Device Name
CS-series-FP with MX CFP 3131 or MX CFP 2222 Option Radiographic / Fluoroscopy System

Indications for Use *(Describe)*
The Omega Medical Imaging, LLC CS-series-FP (SSXI) Systems are intended for use in Radiographic/fluroscopic applications including cardiac, vascular, general radiographic/fluroscopic 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.

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Special 510(k) SUMMARY

Company Name:	Omega Medical Imaging, LLC
Address:	675 Hickman Circle, Sanford, Florida 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	Brian J. Fleming
Date Prepared:	05/26/2017
Device (trade) name:	CS-series-FP with MX CFP 3131 or MX CFP 2222 Option radiographic/fluoroscopy system
Common/usual name:	Fluoroscopic/Radiographic X-ray system
Classification Name:	Solid State X-ray Imager, Class II, 90 MQB
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Device Code:	90 OWB / JAA

Predicate Device(s):

- Omega Medical Imaging CS-series-FP (K121293)

Device description:

The Omega Medical Imaging, LLC, CS-series-FP systems currently incorporate a 19.8cm x 19.8cm or 29.8cm x 29.8cm solid-state flat-panel detector (FPD). This 510(k) submission adds a slightly larger 21.7cm x 21.7cm and 30.3cm x 30.3cm solid-state CMOS flat-panel detector as an additional option. The CS-series-FP fluoroscopy single and dual plane x-ray imaging systems are configured with a floor mounted c-arm and patient table. The dual plane systems incorporate a ceiling suspended C-arm into the system. The MX CFP 3131 flat-panel image detector utilizes a cesium iodide scintillator coupled to an amorphous silicon TFT panel. The captured digital image is processed by the acquisition system (separate from the Flat Panel Detector) which includes image processing, viewing functions, local storage, and DICOM compatibility. The Image Processor does not have the capability to connect to the internet as there is no browser.

Subject Device Flat Panel Detectors MX CFP 2222 / 3131 are to be used only with the Omega CS-series-FP Fluoroscopic Systems

Indications for use:

- The Omega Medical Imaging, LLC CS-series-FP with Optional MX CFP 3131 and MX CFP 2222 are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.
- The intended use of the modified device, as described in the labeling, has not changed as a result of the modification for this filling.

Comparison with Predicate Devices:

- The Omega Medical Imaging MX CFP 2222 and 3131 option the CS-series-FP system utilizes the same technology as the above-mentioned predicate device. The input scintillator is Cesium Iodide coupled to a CMOS-light sensitive imaging component. The image processing is achieved with conventional computer based image processing system that is separate from the Flat Panel Detector. The MX CFP 2222 and 3131 Flat Panel Detectors are manufactured by the same company as the Image Processor. It is the opinion of Omega Medical Imaging that the CS-series-FP with the MX CFP 2222 and MX CFP 3131 option is equivalent to the existing Omega Medical Imaging cleared CS-series-FP system.

Substantial Equivalence:

- **SE** was determined on Bench performance testing. Included in this report is detailed data comparing performance with the existing Omega Medical Imaging CS-series-FP system utilizing the 29.8cm x 29.8cm and 19.8cm x 19.8cm format FPD image acquisition systems. The tests that were performed utilized commercially available Test Object that include low-contrast objects with varying absorbers simulating different patient sizes, spatial and temporal resolution test objects, and dynamic range test objects.
- *Guidance for this submission of 510(k) for (SSXID) Solid State X-ray Imaging Devices issued on: September 1, 2016 was used to establish substantial equivalence*

Safety information:

- The Omega CS-series-FP with the MX CFP 2222 and MX CFP 3131 option systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega CS-series-FP with the MX CFP 2222 and MX CFP 3131 option systems comply with the international safety standards IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32, and IEC 60601-2-43.
- The Omega CS-series-FP with the MX CFP 2121 and MX CFP 3131 option systems comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Conclusion:

The Omega CS-series-FP with the MX CFP 2222 and MX CFP 3131 options do not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the Omega CS-series-FP with the MX CFP 2222 and MX CFP 3131 Flat panel detectors to be substantially equivalent with the predicate device.

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