July 19, 2018

Canon Medical Systems Corporation
% Mr. Paul Biggins
Senior Director Regulatory Affairs
Canon Medical Systems, U.S., Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K181834
Trade/Device Name: Ultimax-i, DREX-UI80, V1.60
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: July 6, 2018
Received: July 10, 2018

Dear Mr. Biggins:

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 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,

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)*
k181834

Device Name

Ultimax-i, DREX-UI80, V1.60

Indications for Use *(Describe)*

The Ultimax-i multipurpose digital X-ray system is designed for gastrointestinal studies, vascular studies, general radiography, and fluoroscopy.

The Ultimax-i system has medical applications ranging from but not limited to: contrast-enhanced studies, support of endoscopic studies, nonvascular contrast-enhanced studies, nonvascular IVR , vascular contrast-enhanced studies, support of vascular IVR, and general radiography.

Note: This system is not intended for cardiovascular contrast studies or interventional radiology procedures for the cardiac or cerebral blood vessels.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

1. **CLASSIFICATION and DEVICE NAME**

Classification Name	**Image Intensified Fluoroscopic X-Ray System**
Regulation Number	**21 CFR § 892.1650 (Class II)**
Product Code	**OWB - Interventional Fluoroscopic X-ray System (Primary)** **JAA - Image-Intensified Fluoroscopic X-Ray System (Secondary)**
Trade Proprietary Name	**Ultimax-i**
Model Number	**DREX-UI80**

2. **SUBMITTER'S NAME**

Canon Medical Systems Corporation
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Otawara-Shi, Tochigi-ken, Japan 324-8550

3. **OFFICIAL CORRESPONDENT**

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5. **MANUFACTURING SITE**

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6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

July 6, 2018

8. **DEVICE NAME**

Ultimax-i, DREX-UI80, V1.60

9. **TRADE NAME**

Ultimax-i, DREX-UI80, V1.60

10. **CLASSIFICATION NAME**

Image-Intensified Fluoroscopic X-Ray System

11. CLASSIFICATION PANEL

Radiology

12. DEVICE CLASSIFICATION

Class II (Per 21 CFR § 892.1650)

13. PRODUCT CODE / DESCRIPTION

OWB - Interventional Fluoroscopic X-ray System (Primary)
JAA - Image Intensified Fluoroscopic X-Ray System (Secondary)

14. PERFORMANCE STANDARD

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

15. PREDICATE DEVICE

Ultimax-i, DREX-UI80, V1.31 (K170832)

Reference Predicate
DelWorks DR System (K140825

System	Subject	Primary Predicate	Reference Predicate
	Ultimax-I, DREX UI80 Version 1.60	Ultimax-I, DREX UI80 Version 1.60	DelWorks DR System
Manufacturer	Canon Medical Systems Corporation	Canon Medical Systems Corporation	Del Medical
510(k) Number	TBD	K170832	K140825
Clearance Date		July 21, 2017	July 17, 2014
Regulation Number (classification code)	21 CFR § 892.1650 (Class II)	21 CFR § 892.1650 (Class II)	21 CFR § 892.1650 (Class II)
Product Code	OWB/JAA	OWB/JAA	KPR/MQB

16. REASON FOR SUBMISSION

Modification of a cleared device

17. SUBMISSION TYPE

Special 510(k)

18. DEVICE DESCRIPTION

Ultimax-i, DREX-UI80, is a fixed C-arm fluoroscopic device intended to provide radiographic and fluoroscopic images in a variety of studies. The unit consists of a C-arm with X-ray tube, beam limiter and digital flat panel detector (FPD), a wireless flat panel detector, a patient table that can tilt in both directions, an 80kW X-ray generator, an overhead tube support assembly, an image processor and both remote and table side control.

19. INDICATIONS FOR USE

The Ultimax-i multipurpose digital X-ray system is designed for gastrointestinal studies, vascular studies, general radiography, and fluoroscopy.

The Ultimax-i system has medical applications ranging from but not limited to: contrast-enhanced studies, support of endoscopic studies, nonvascular contrast-enhanced studies, nonvascular IVR, vascular contrast-enhanced studies, support of vascular IVR, and general radiography.

Note: This system is not intended for cardiovascular contrast studies or interventional radiology procedures for the cardiac or cerebral blood vessels. This system is not intended for mammography studies in the US.

20. SUMMARY OF CHANGE(S)

This submission is to report modifications made to the Ultimax-i system consisting of the addition of the TFP-1417W wireless general radiography solid state x-ray detector. This detector allows for one detector to be used in the table bucky, the wall stand and other x-ray exams outside of a standard holder. This detector was cleared under the reference predicate via K140825. The software remains unchanged from the predicate device submission K170832.

21. SAFETY

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards, its collateral standards and particular standards; IEC 60601-2-54, IEC60601-2-43 and IEC 60601-2-28. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report. Additionally, this device meets the applicable requirements of the Food and Drug Administration Guidance Document "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, September 1, 2016"

LIST OF APPLICABLE STANDARDS

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60602-1-3: 2008
- IEC60601-1-6: 2010
- IEC60601-2-28: 2010
- IEC60601-2-43:2010
- IEC60601-2-54:2009
- IEC62304:2006
- IEC62366:2007
- IEC60825-1:2007
- IEC60627:2001
- IEC62494-1:2008

22. TESTING

This submission contains integration test data that demonstrates that the system modifications result in performance that is equal to or better than the predicate system. Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems. Software testing was not conducted as the software version 1.6 was not changed. Additionally, the design controls used for this device included risk management and all known risks were mitigated to an acceptable level.

23. SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the Ultimax-i, DREX-UI80, V1.60, in that the introduction of the portable x-ray detector does not change the operational capabilities of the system, the intended use of the system and the indications for use.

24. CONCLUSION

The subject device is substantially equivalent to the Ultimax-i, DREX-UI80, V1.60 which was cleared via Pre-Market Notification 510(k), K170832. The Ultimax-i, DREX-UI80, V1.60, incorporates a modification to the cleared device in the addition of a wireless general radiography x-ray solid state detector. The change to this device do not alter the indications for use or the intended uses associated with the previously cleared device, as described in the labeling. It is the contention of Canon Medical Systems Corporation that all new safety issues have been addressed in the design of this change and that adequate evidence of this is presented with this submission.