December 19, 2019

Shanghai United Imaging Healthcare Co., Ltd.
% Shumei Wang
QM & RA VP
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, Shanghai 201807
CHINA

Re: K183144
Trade/Device Name: uMC 560i
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: November 27, 2018
Received: November 29, 2018

Dear Shumei Wang:

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,

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)*
K183144

Device Name
uMC 560i

Indications for Use *(Describe)*
The uMC 560i is intended to provide digital imaging of patients during diagnostic and surgical procedures. Examples of clinical application may include, but are not limited to: orthopedic, pain therapy, neurological, pediatric examinations and critical care. The visualization of such anatomical structures assists the clinician with clinical decisions. This device does not support direct radiographic film exposures and is not intended for use in performing 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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**510 (k) SUMMARY** K183144

1. **Date of Preparation:**
   November 26, 2019

2. **Sponsor Identification**

   **Shanghai United Imaging Healthcare Co.,Ltd.**

   No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

   Establishment Registration Number: 3011015597

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3. **Identification of Proposed Device**

   **Trade Name:** uMC 560i
   **Common Name:** Mobile C-arm X-Ray System
   **Model(s):** uMC 560i
   **Regulatory Information**
   **Classification Name:** Image-intensified fluoroscopic x-ray system
   **Classification:**
   **Product Code:** OWB, OXO, JAA
   **Regulation Number:** 21 CFR 892.1650
   **Review Panel:** Radiology

4. **Identification of Predicate Device(s)**

   **Predicate Device**
   **510(k) Number:** K153244
   **Device Name:** Cios Fusion
   **Manufacturer:** Siemens AG
   **Regulatory Information**
   **Classification Name:** Image-intensified fluoroscopic x-ray system
   **Classification:** II
   **Product Code:** OWB, OXO
   **Regulation Number:** 21 CFR 892.1650
   **Review Panel:** Radiology
   **Reference Device**

**510(k) Number:** K181560
**Device Name:** Cios Alpha
**Manufacturer:** Siemens AG

**Regulatory Information**
**Classification Name:** Image-intensified fluoroscopic x-ray system
**Classification:** II
**Product Code:** OWB, OXO
**Regulation Number:** 21 CFR 892. 1650
**Review Panel:** Radiology

## 5. Device Description

uMC 560i is the first mobile C-arm X-ray system developed and produced by UIH Medical XR Business Unit. It is designed to meet medical institutions' demands. To cover the most surgical imaging needs, it's X-ray imaging of the anatomical structures of patient during clinical applications may include, but are not limited to: orthopedic, pain therapy, neurological, pediatric examinations and critical care. uMC 560i consists of C-arm, Monoblock, Anti-scatter Grid, CMOS flat panel detector, Collimator system, Exposure handswitch, Exposure footswitch, Connects cables for Monitor cart and C-arm mobiles stand, Monitor cart, Touchable control panel, HD monitor, Examination workstation. The powerful system performance brings a safe, fluent and efficient operation experience.

## 6. Indications for Use

The uMC 560i is intended to provide digital imaging of patients during diagnostic and surgical procedures. Examples of clinical application may include, but are not limited to: orthopedic, pain therapy, neurological, pediatric examinations and critical care. The visualization of such anatomical structures assists the clinician with clinical decisions. This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

## 7. Performance Data

### Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electric for basic safety and essential performance (IEC 60601-1:2005, MOD).
- 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.

- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- IEC 60601-2-28 Edition 2.0 2010-03 Medical electrical equipment –Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.
- IEC 60601-2-43 Edition 2.1 2017-05 CONSOLIDATED VERSION Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures.
- IEC 60601-2-54 CONSOLIDATED VERSION Edition 1.1 2015-04 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 Edition 1.1 2015-06 Medical device software - Software life cycle processes.
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

**Clinical Test Conclusion**

The fluoroscopy sequences images and static images produced by the uMC 560i in clinical environment accompanied by exposure mode, exposure parameters and anatomical regions were provided in the clinical evaluation. Both dynamic and static images were reviewed by a board-certified clinical reviewer with a statement indicating that images are of diagnostic quality.

## 8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Device Functionality and Specification

| ITEM | Proposed Device<br>uMC 560i | Predicate Device<br>Siemens Cios Fusion<br>(K153244) | Remark |
|---|---|---|---|
| **General** | | | |
| Mobile Fluoroscopic C-arm | Yes | Yes | Same |
| Product Code | OWB, OXO | OWB, OXO | Same |
| Class | II | II | Same |
| Indications for Use | The uMC 560i is intended to provide digital imaging of patients during diagnostic and surgical procedures. Examples of clinical application may include, but | The Cios Fusion is a mobile X-Ray System designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may | Note 1 |

| | | | |
|---|---|---|---|
| | are not limited to: orthopedic, pain therapy, neurological, pediatric examinations and critical care. The visualization of such anatomical structures assists the clinician with clinical decisions. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. | include but are not limited to: interventional fluoroscopic, gastrointestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients. | |
| **Specifications** | | | |
| Imaging Modes | • Pulsed Fluoroscopy<br>• Spot Fluoroscopy<br>• Digital Radiography | • Pulsed Fluoroscopy<br>• Continuous Fluoroscopy<br>• Digital Radiography | Note 2 |
| X-ray Tube | Stationary Anode | Stationary Anode | Same |
| X-ray Generator and Tube Housing Assembly Monoblock Technology | Yes | Yes | Same |
| KV Range | 40 kV – 110 kV | 40 kV – 110 kV | Same |
| Max Power Output | 3.5 kW | 2.3 kW | Note 3 |
| Pulsed Fluoroscopy Current | 0.1 mA - 30 mA | 3 mA - 25 mA | Note 4 |
| Displays | 34” TFT Flat Screen Color Display Panel | 19” TFT Flat Screen Color Display Panels | Note 5 |
| Collimator | Yes, Pd, Rectangular and Slot Collimator | Yes, Pd, Rectangular and Slot Collimator | Same |
| SID | 107.5 cm | 102 cm | Note 6 |
| Removable Anti-scatter Grid | Yes | Yes | Same |
| Dose Area Product | Yes | Yes | Same |
| Monitor Cart | Mandatory Monitor Cart | Mandatory Monitor Cart | Same |
| User Interface | Yes, Touch Panel | Yes, Touch Panel | Same |
| Dose Optimization | uFree Dose Management Technology | Siemens CARE Program | Note 7 |
| DICOM Function | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| 2D Image Post Processing | Yes | Yes | Same |
| **Safety** | | | |
| Electrical Safety | AAMI ANSI ES60601-1:C1:2009/(R)2012 and A2:2010/(R)2012 | Comply with AAMI/ANSI ES 60601-1(IEC 60601-1:2005) | Same |
| EMC | Comply with IEC60601-1-2 | Comply with IEC60601-1-2 | Same |
| Biocompatibility | Comply with ISO10993-5, ISO10993-10 | Comply with ISO10993-5, ISO10993-10 | Same |

Table 2 Comparison of Flat Panel Detector Specification

| ITEM | Proposed Device<br>uMC 560i | Reference Device<br>Siemens Cios Alpha (K181560) | Remark |
|---|---|---|---|
| **Specifications of Flat Panel Detector** | | | |
| Image Receptor | CMOS Flat Panel Detector XINEOS 2222HS | CMOS Flat Panel Detector XINEOS 3030HS or XINEOS 2222HS | Same |
| DQE | 75% | 75% (XINEOS 2222HS)<br>72% (XINEOS 3030HS) | Same |
| Dynamic Range | 96dB | 96dB | Same |
| Modulation Transfer Function (MTF) | 60%@1lp/mm | 60%@1lp/mm(XINEOS 2222HS)<br>58%@1lp/mm(XINEOS 3030HS) | Same |
| Digitization Depth | 16bit | 16bit | Same |
| Field of View | Square, 21.5 cm ×21.5 cm | Square, 20 cm ×20 cm (XINEOS 2222HS)<br>Square, 30 cm ×30 cm (XINEOS 3030HS) | Note 8 |
| Pixel Size | 151.8 μm | 152 μm | Same |
| Matrix Size | 1416 ×1420 | 1416 ×1420 (XINEOS 2222HS)<br>1952×1952 (XINEOS 3030HS) | Same |

Table 3 Justifications of Differences

| Note ID | Justification |
|---|---|
| Note 1 | uMC 560i and the predicate devices are all used for providing digital imaging of adults and pediatric during diagnostic and surgical procedures. The difference is that uMC 560i is not intended to be used during interventional, which does not affect the clinical application of uMC 560i. The difference does not affect safety and effectiveness. |

| | |
|---|---|
| Note 2 | Compared to predicate devices Siemens Cios Fusion (K153244),<br>• uMC 560i does not provide continuous fluoroscopy, whose fundamental principle and clinical application are the same with pulsed fluoroscopy. The difference does not affect safety and effectiveness.<br>• uMC 560i also provides spot fluoroscopy, whose fundamental principle is the same with pulsed fluoroscopy. The difference between spot fluoroscopy and pulsed fluoroscopy is that radiation stops automatically when meeting target grey level, but the image quality is the same with LIH of pulsed fluoroscopy. The difference does not affect safety and effectiveness. |
| Note 3 | 3.5 kW has the ability to provide higher mA at lower kV levels allowing shorter pulse widths at variable frame rates to increase the image quality of moving objects by reducing or eliminating the movement during each single pulse. The difference in maximum power output does not affect safety and effectiveness. |
| Note 4 | The pulsed fluoroscopy current of predicate devices can be covered by uMC 560i's in clinical application. And the maximum current of uMC 560i is larger than predicate devices, which will improve the image quality of large patient. The difference in pulsed fluoroscopy current does not affect safety and effectiveness. |
| Note 5 | The display with larger size will improve user experience, which does not affect safety and effectiveness. |
| Note 6 | The slight difference of SID does not affect clinical application. The difference does not affect safety and effectiveness. |
| Note 7 | uMC 560i and the predicate devices all provide dose optimization method. Even though the principle is different, the effectiveness of uFree can be proven by Section 21 Software Design Description (Chapter 3.3.8). The difference does not affect safety and effectiveness. |
| Note 8 | uMC 560i and the reference device (K181560) both use the same flat panel detector. uMC 560i has a larger effective imaging area than Cios Alpha. The slight difference of Field of View does not affect clinical application. The difference does not affect safety and effectiveness. |

## 9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device has same intended use, similar performance, equivalence safety and effectiveness as the predicate device. The differences above between the proposed device and predicate device do not affect the intended use, technology characteristics, safety and effectiveness. And no issues are raised regarding to safety and effectiveness.

The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.