December 18, 2018

Konica Minolta, Inc.
℅ Russell D. Munves
U.S. Agent
STORCH AMINI PC
140 East 45th Street, 25th Floor
NEW YORK, NY 10017

Re: K182688
   Trade/Device Name: SKR 3000
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: Class II
   Product Code: MQB, LLZ
   Dated: September 25, 2018
   Received: September 26, 2018

Dear Russell Munves:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

[Signature]

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K182688

Device Name
SKR 3000

Indications for Use (Describe)
The SKR 3000 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures.

The SKR 3000 is not indicated for use in mammography, fluoroscopy and angiography applications.

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

Submitter’s Name: KONICA MINOLTA, INC.

Address: 1 Sakura-machi,
Hino-shi, 191-8511 Japan

Contact: Tsutomu Fukui

Telephone: +81 42 589 8429

Date: November 26, 2018

Trade Name: SKR 3000

Model No: P-61, P-71, P-81

Common Name: Digital Radiography

Regulation Name / Number: Stationary x-ray system / 21 CFR 892.1680

Regulatory Class: Class II

Product Code(s): 90-MQB, 90-LLZ

Predicate Device(s): K172793 - SKR 3000 (KONICA MINOLTA, INC.)

Regulation Name: Stationary x-ray system (21CFR 892.1680),
Product Codes: 90-MQB, 90-LLZ

Device Description:

The modified SKR 3000 employs additional peripheral units, the Detector Interface Unit 2 (DIU2) and the Generator Interface Units 3 (GIU3), to incorporate serial radiography operation that is an additional radiography acquisition sequence.

The system is intended for use replacing a radiographic film/screen system in general-purpose diagnostic procedures of human anatomy. The system can be used in conjunction with current cleared AeroDR FPDs. The P-61, P-71, P-81 and the other compatible FPDs available in SKR 3000 are lightweight, mobile FPD and they are formed in compatible size with the cassette of ISO standard size. The FPDs available for the serial radiography are P-61 and P-71.
The SKR 3000 performs radiography imaging of the human body using an X-ray planar detector (FPD) that outputs a digital signal, which is then input into an image processing device. The serial radiography is a function of multi-frame radiography simply repeating single still radiography multiple times. The acquired image is transmitted to a filing system, printer, and image display device as diagnostic image after applying image processing to the raw data of image by the image processing device, Console CS-7.

The radiography sequences to be synchronized with a trigger timing of X-ray irradiation are the same as the way of predicate device that requires the SRM / S-SRM connection between the SKR 3000 and X-ray generator. The AeroSync allows to use a FPD without a wired connection of SRM / S-SRM, the FPD itself begins to acquire an image when it detects X-ray irradiation in this mode. The AeroSync is not available for the serial radiography.

**Serial Radiography**

<table>
<thead>
<tr>
<th>Applicable FPD</th>
<th>P-61, P-71</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. frame rate</td>
<td>15 fps</td>
</tr>
<tr>
<td>Max. acquisition time</td>
<td>20 seconds</td>
</tr>
<tr>
<td>Max. number of acquisition</td>
<td>300 frames</td>
</tr>
<tr>
<td>Max. per-frame exposure time</td>
<td>“frame-interval-time” – “frame readout time (constant)&quot; milliseconds</td>
</tr>
<tr>
<td>Pixel size (binning)</td>
<td>400 µm (4 X 4)</td>
</tr>
</tbody>
</table>

The basic operation of serial radiography is the same as conventional still radiography, but using a pulsed x-ray generator. The patient information and orders of examination are set, the conditions of X-ray irradiation are set through the console of the X-ray generator, then exposure is executed. By pressing and holding the exposure button, sequential frames are acquired in accordance with user selected parameters. The adjustment of image processing parameters and reviewing sequential images are available by the user before the image data is output to the host. The SKR 3000 does not permit “live imaging” unlike a fluoroscopic device.

There are restrictions on operation such as not being able to apply some image processing functions, besides being unable to use the high image quality monitor that can be used for conventional still radiography, it is necessary to confirm with the operation manual before use.

The compatible X-ray system is same as that of previously cleared SKR 3000. Additionally, the X-ray devices used for the serial radiography need to be capable for generating pulsed x-ray output and must be compatible to connect with UEC2 board of GIU3 unit.
The FPDs used in SKR 3000 can communicate with the image processing device through the wired Ethernet and/or the Wireless LAN (IEEE802.11a/n and FCC compliant). The WPA2-PSK (AES) encryption is adopted for a security of wireless connection. The SKR 3000 is designed to comply with the following standards; AAMI/ANSI ES 60601-1 (Ed.3.1), IEC 60601-1-2, and ISO 10993-1.

Indications for Use:

The SKR 3000 is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in general-purpose diagnostic procedures. The SKR 3000 is not indicated for use in mammography, fluoroscopy and angiography applications.

Predicate Comparison Table:

<table>
<thead>
<tr>
<th></th>
<th>KONICA MINOLTA SKR 3000</th>
<th>KONICA MINOLTA SKR 3000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(K) Control Number</strong></td>
<td>Proposed device</td>
<td>K172793</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>Same as Predicate device</td>
<td>Same as Predicate device</td>
</tr>
<tr>
<td><strong>Specification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detection method</td>
<td>Same as Predicate device</td>
<td>Indirect conversion method</td>
</tr>
<tr>
<td>Scintillator</td>
<td>Same as Predicate device</td>
<td>CsI (Cesium Iodide)</td>
</tr>
<tr>
<td>Image area size</td>
<td>Same as Predicate device</td>
<td>P-61: 348.8×425.6mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(3,488×4,256 pixels)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P-71: 424.8×424.8mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4,248×4,248 pixels)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P-81: 245.6×296.8mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2,456×2,968 pixels)</td>
</tr>
<tr>
<td>Pixel size</td>
<td>100 μm / 200 μm / 400 μm</td>
<td>100 μm / 200 μm</td>
</tr>
<tr>
<td>A/D conversion</td>
<td>Same as Predicate device</td>
<td>16 bit (65,536 gradients)</td>
</tr>
<tr>
<td><strong>Mechanical</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External dimensions</td>
<td>Same as Predicate device</td>
<td>P-61: 384(W)×460(D)×15(H)mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P-71: 460(W)×460(D)×15(H)mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>P-81: 282(W)×333(D)×15(H)mm</td>
</tr>
<tr>
<td>IPX</td>
<td>Same as Predicate device</td>
<td>IPX6</td>
</tr>
<tr>
<td><strong>Communication I/F</strong></td>
<td>Same as Predicate device</td>
<td></td>
</tr>
<tr>
<td><strong>Operator console</strong></td>
<td>OTS Desktop PC and Laptop PC, the higher specification is required for serial radiography.</td>
<td>OTS Desk Top PC and Laptop PC</td>
</tr>
</tbody>
</table>
Compatible X-ray System Spec. | KONICA MINOLTA SKR 3000 | KONICA MINOLTA SKR 3000
--- | --- | ---
510(K) Control Number | Proposed device | K172793

The SKR 3000 can be connected with X-ray devices being compatible with XIF, XGIF, UEC or UEC2 board along with certain electronic requirement such as specific signal controls for hardware and software. The X-ray device used for serial radiography needs to be capable for generating pulsed x-ray output and must be compatible to connect with UEC2 board.

The SKR 3000 can be connected with X-ray devices being compatible with XIF, XGIF or UEC board along with certain electronic requirement such as specific signal controls for hardware and software.

Summary of Technological Characteristics
Compared to Predicate Device:

The discussion of substantial equivalence based on comparisons of indication for use, technologies, and performance characteristics for both systems are provided as follows;

**Operational principles and designing:**
The system has same scientific technologies and operational principal as the predicate device (K172793). The additional peripheral components, DIU2 and GIU3, employs equivalent function of the similar components of the predicate device, and complies with same EMC and electrical safety standards. The proposed device is essentially the same as previously cleared predicate device from technology view point. The serial radiography, a modified radiography sequence, is evaluated and concluded that it does not raise any new issues of safety and effectiveness through design activities. All of the verification activities required by the specification and the risk analysis for the SKR 3000 were performed and the results demonstrated that the predetermined acceptance criteria were met.

**Performance test:**
The performance tests according to the “Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices” and the other verification and validation including the items required by the risk analysis for the SKR
3000 were performed and the results demonstrated that the predetermined acceptance criteria were met.

The concurrence study is not necessary because the proposed modifications are categorized as the type of unnecessary to provide additional clinical data in accordance with the SSXI guidance. Besides, the results of risk management did not require clinical studies to demonstrate the substantial equivalency of the proposed device.

**Safety:**
The system is in conformance with the standards described above, which are same standards to those of predicate device.
The Risk Analysis for the SKR 3000 has been conducted in accordance with the SOP conforming to ISO 14971. The risks associated with all the identified hazards including serial radiography were reduced to acceptable level by the risk control measures as shown in Risk Assessment Record.

**Biocompatibility:**
There is no material change in patient contact materials for human body surface at all.

**Conclusion:**
The clinical study as a performance testing is not required to support substantial equivalence for the proposed device. In addition, as discussed in the above technological comparison, the technological characteristics of the SKR 3000 are deemed to be substantially equivalent to the predicate device that have already been cleared for USA distribution with 510(k) premarket notification number K172793.