



July 13, 2018

Biokinometrics Inc.
% Steven Kraus
President
211 East 4th Street
CARROLL IA 51401

Re: K181565
Trade/Device Name: AQUARIUS 8600 Digital Radiography Sensor
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 13, 2018
Received: June 14, 2018

Dear Steven Kraus:

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,

A handwritten signature in black ink, appearing to read "Rob 2. Ochs", is written over a large, semi-transparent blue "FDA" watermark.

Robert 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)

K181565

Device Name

AQUARIUS 8600 Digital Radiography Sensor

Indications for Use (Describe)

The AQUARIUS 8600 is intended for use by a qualified doctor or technologist on both adult and paediatric patients for taking diagnostic radiographic exposures of all body parts of the patients. The AQUARIUS 8600 provides digital image capture and is intended to replace radiographic film/screen. The x-ray generator, x-ray tube and associated equipment are not provided with the proposed sensor. Prescription use only.

The AQUARIUS 8600 is not intended for 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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SPECIAL 510K – SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device type and name: Aquarius 8600 Digital Radiography Sensor
Common name: Aquarius 8600

2. Submitter: Biokinometrics Inc.
211 East 4th Street
Carroll Iowa 51401

Contact person: Dr. Steven Kraus
President
Tel: (712) 210-4750
Fax: (888) 800-2149
e-mail: skraus@biokinometrics.com

Date prepared: June 12, 2018

3. Device classification: 21 CFR 892.1680, Stationary x-ray system

4. Product Code: 90/MQB

5. Basis for the submission: Software modifications to support
Aquarius 8600 Flat Panel Detector.

6. Predicate devices: Primary: Aquarius 8600 Flat Panel Detector (K170202)
For the ChiroSight software:
BIOK4600 Digital Radiography Sensor (K092307)
*same classification & product code: 21 CFR 892.1680, 90/MQB,
KPR

7. Device description: The Aquarius 8600 is a digital radiography sensor which automatically collects x-ray images from an x-ray source. The Aquarius 8600 sensor (flat panel type) collects x-rays and digitizes the images for their transfer and display to a computer. The sensor does not have an x-ray source, which is provided by independent manufacturers. The sensor includes with a flat panel for x-ray acquisition and digitization and a computer (including proprietary processing software) for processing, annotating and storing x-ray images.

An x-ray generator with a minimum voltage output range between 55 to 120 kVp and a minimum power of 30 KW can be used with the Aquarius 8600. The Aquarius 8600 does not connect to the generator. It automatically detects x-rays and enables the image acquisition. No changes to the generator hardware or software are required to operate the Aquarius 8600.

8. Indications for use: The Aquarius 8600 is intended for use by a qualified doctor or technologist on both adult and paediatric patients for taking diagnostic radiographic exposures of all body parts of the patients. The Aquarius 8600 provides digital image capture and is intended to replace radiographic film/screen. The x-ray generator, x-ray tube and associated equipment are not provided with the proposed sensor. Prescription use only. The Aquarius 8600 is not intended for mammography.

9. Comparison with predicate devices: The Aquarius 8600 is composed of the Aquarius 8600 predicate device hardware and the BIOC4600 software on the PC. The hardware and firmware of the Aquarius 8600 flat panel is UNMODIFIED and is considered to be substantially equivalent to the Aquarius 8600 predicate device hardware. The Aquarius 8600 software functionality is equivalent to the original BIOC4600 predicate device, except for the Sensor Driver interface application which reads the images from the Aquarius 8600 flat panel instead of the BIOC 4600 sensor. The Aquarius 8600 produces images of similar quality and characteristics that are equivalent to those of the both the Aquarius 8600 and BIOC4600 predicate devices.
 - a. Non-clinical tests: Because the sensor hardware is the same as the Aquarius 8600 predicate device hardware, the sensor has the same performance, biocompatibility, effectiveness, thermal, electrical and mechanical safety and is substantially equivalent to the predicate device. The design, development and production of the sensor conforms to 892.1680 and ISO 13485 quality systems.
 - b. Image Comparison: Test images have been submitted along with the equivalent images from the Aquarius 8600 predicate device.
 - c. Conclusion: the device was evaluated against both predicate devices (BIOC4600 and Aquarius 8600) and was found to be substantially equivalent to the predicate devices.

10. Technological Characteristics:

X-Ray Equipment (Generator, Tube)	Not provided by Biokinometrics
Flat Panel Sensor	<p>AQUARIUS 8600 Flat Panel Detector array size: 17" x 17" (423mm x 423mm) TFT matrix: (3328 x 3328 pixels)</p> <p>Spatial resolution: 3.9 lp/mm Optical resolution: 3.9 lp/mm Acquisition to display time: < 2 sec Network interface: 1000 mbps LAN Image and file formats: DICOM compliant Power: 24Vdc, 1.9A max (18W typ)</p>
PC	<p>Dell Optiplex 7050, small form factor 128GB SSD + 2TB HDD 8GB memory Full HD video capability HDMI, DisplayPort output i5 or i7 intel CPU (or equivalent) 2x LAN connections (10/100/1000)</p>
PC software:	ChiroSight software