Biokinemetrics Inc.
% Steven Kraus
President
211 East 4th Street
CARROLL IOWA 51401

March 13, 2019

Re: K190300
Trade/Device Name: BIOK7600W Wireless Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: February 9, 2019
Received: February 12, 2019

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. 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); 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,

For

Thalia Mills, 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)*
K190300

Device Name
BIOK7600W Wireless Flat Panel Detector

Indications for Use *(Describe)*
The BIOK7600W is intended for use by a qualified doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of all body parts of the patients. The BIOK7600W 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 BIOK7600W 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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ALIGNING CHIROPRACTIC AND TECHNOLOGY

TRADITIONAL 510K – SUMMARY (K190300)

1. Device type and name: BIOK7600W Wireless Flat Panel Detector

2. Submitter

Biokinemetrics 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@biokinemetrics.com

Date prepared: March 7, 2019

3. Device name: BIOK7600W Wireless Flat Panel Detector
Common name: BIOK7600W

4. Device classification: Class II, 21 CFR 892.1680, Solid-State X-ray Imager (Flat panel/ Digital Imager)

5. Product Code: 90MQB

6. Regulation Name: Stationary x-ray system

7. Basis for the submission: Addition of a sensor to the list of medical devices compatible with the Biokinemetrics devices

8. Predicate device: Wireless Digital Flat Panel Detector (K182551) with iRay software
Reference: BIOK4600 Digital Radiography Sensor (K092307)
Reference: Aquarius 8600 Flat Panel Detector (K181565)
*same classification & code: Class II, 21 CFR 892.1680, 90MQB

9. Device description: The BIOK7600W sensor is a wireless digital radiography sensor which automatically collects x-ray images from an x-ray source. The BIOK7600W 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 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 BIOK7600. The BIOK7600 does not connect to the generator. It automatically detects x-rays and enables the image acquisition (AEC). No changes to the generator hardware or software are required to operate the BIOK7600.

The ChiroSight software runs on a PC workstation and provides the user interface to control the BIOK7600 flat panel. ChiroSight initiates the taking of X-ray images from the BIOK7600, through the Sensor Driver application. Once an X-ray is taken, Sensor Driver reads it from the flat panel and transfers it to ChiroSight. After it receives an image from the BIOK7600, ChiroSight:

Automatically optimizes the image quality
Permanently stores the image to its database
Displays the image to the user
Allows the user to perform image manipulations and to add annotations
Allows the user store and transfer the images in DICOM format.

The software level of concern for the BIOK7600 has been determined to be moderate based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The cybersecurity risks of the BIOK7600 have been addressed to assure that no new or increased cybersecurity risks were introduced as a part of device risk analysis. These risks are defined as sequence of events leading to a hazardous situation, and the controls for these risks were treated and implemented as proposed in the risk analysis (e.g., requirements, verification).

10. Indications for use: The BIOK7600W 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 BIOK7600W is not intended for mammography.

11. Comparison with predicate devices: The BIOK7600W sensor is composed of a flat panel detector very similar to the technology used in the Wireless Digital Flat Panel Detector (K182551, predicate device hardware) and the BIOK4600 (K092307) software on the PC. The hardware and firmware of the BIOK7600W sensor are considered to be substantially equivalent to the predicate device hardware, as demonstrated in the non-clinical considerations document, based on the SSXI Guidance from FDA. The BIOK7600W software functionality is equivalent to the original BIOK4600 reference device, except for the Imaray interface application which reads the images from the new BIOK7600W sensor instead of the BIOK 4600 sensor. The BIOK7600W produces images of similar quality and characteristics that are equivalent to those of the predicate device, as demonstrated in the clinical considerations – concurrence study provided in this submission.
    a. Non-clinical considerations: the non-clinical considerations document demonstrates that the BIOK7600W sensor offers equivalent performance, biocompatibility, effectiveness, thermal, electrical and mechanical safety and is equivalent to the predicate device. The design, development and production of the sensor conforms to 892.1680 and ISO 13485 quality systems.
    b. Clinical considerations – concurrence study: A set of test images have been submitted along with the equivalent images from the predicate device.

c. Conclusion: the device was evaluated against the predicate device (Wireless Digital Flat Panel Detector, K182551) and was found to be equivalent to the predicate device.