October 31, 2018

Halifax Biomedical, Inc.
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

Re: K182880
Trade/Device Name: Halifax Imaging Kit
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB, LLZ
Dated: October 11, 2018
Received: October 15, 2018

Dear Daniel Kamm:

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,

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

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)*
K18 2880

Device Name
Halifax Imaging Kit

Indications for Use *(Describe)*
This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures). Not 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K182880

Halifax Biomedical Inc.
11493 Route 19, Mabou
Nova Scotia, Canada, B0E 1X0
Phone +1 902 945 2762
Fax +1 902 945 2324
Chad Munro, CEO, President
Date Prepared: October 30, 2018

1. **Identification of the Device**:
   Proprietary-Trade Name: Halifax Imaging Kit
   Regulation Number: 892.1680
   Regulation Name: Stationary x-ray system.
   Regulatory Class: II
   Product Codes: KPR, MQB, LLZ
   Common/Usual Name: Stationary X-Ray System

2. **Equivalent legally marketed device**: Halifax SR Suite 1.0, K121345
   Regulation Number: 892.1680
   Regulation Name: Stationary x-ray system.
   Regulatory Class: II
   Product Codes: KPR, MQB, LLZ
   Common/Usual Name: Stationary X-Ray System

3. **Contact**:
   Daniel Kamm, P.E., Tel 239-234-1735, Email fda.help.now@gmail.com

4. **Indications for Use**: This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures). Not for mammography.

5. **Description of the Device:** The Halifax SR Suite consists of two X-Ray imaging systems; the two systems are integrated through a synchronization switch. The switch allows the two X-Ray imaging systems to fire simultaneously, providing a pair of X-Ray images from different perspectives to be taken at the exact same time. This process allows for Roentgen Stereophotogrammetric Analysis (RSA). RSA is a stereo x-ray technique that enables measurements more precise than single plane radiography based on phantom precision studies. The resulting level of precision provides measurements of joint replacement stability.

   The Halifax Imaging Kit is part of the SR Suite product line and provides an alternative path to creating an SR Suite. The Halifax Imaging Kit consists of FDA cleared and/or certified X-Ray components integrated into an existing digital radiography room already containing an FDA cleared x-ray imaging system to form an SR Suite. The exposures of the Halifax Imaging Kit and the existing Digital Radiography (DR) system are synchronized by replacing the trigger switches of the two systems with either the Universal Synchronization Switch or the Imaging Kit Control Module (IKCM).

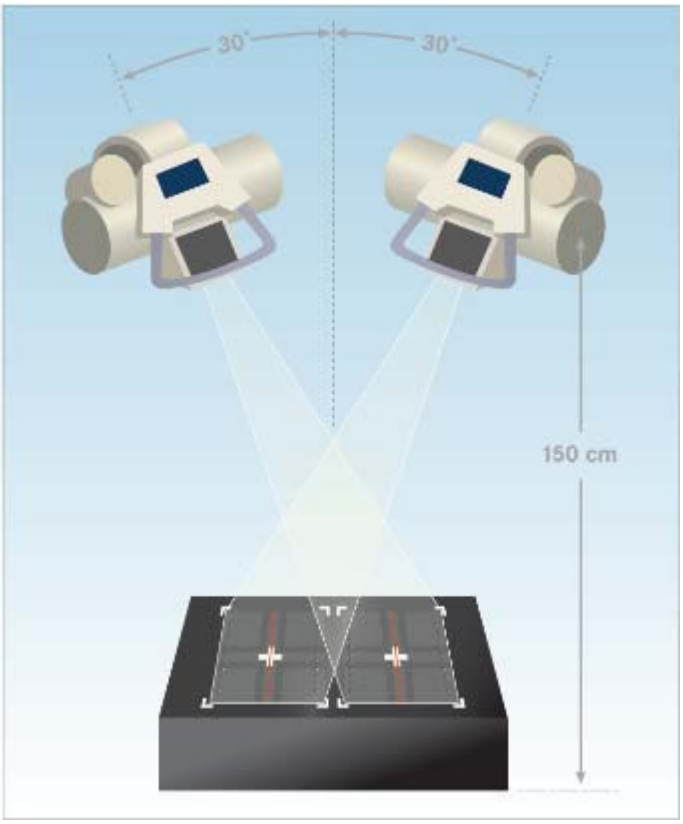
The Universal Synchronization Switch or IKCM ensures the two X-Ray imaging systems fire simultaneously, therefore providing a pair of X-Ray images from two different perspectives taken at the exact same time. There are two versions of the Halifax Imaging Kits:

a) UNIVERSAL SYNCHRONIZATION (NON-GE BASED CONFIGURATION) The Universal Synchronization Switch synchronizes two independent X-ray systems as accurately as possible by using the manual pushbutton interface of each X-ray system. This replaces the synchronization switch that was described in our predicate K121345.

b) IMAGING KIT CONTROL MODULE (GE BASED CONFIGURATION) The general purpose of the IKCM is to coordinate and control the activities of the detector and workstation with the activities of the generator, as well as coordinate the exposures between the client's clinical system and the Halifax Imaging Kit for RSA exposures. The current version of the IKCM is designed specifically for interfacing with the following components:

•GEHC WDR1 Upgrade Kit which consists of a 'Flashpad' detector, a workstation named 'MagicPC', and a 'Cabinet' for power distribution and communication control. Integrating with a pre-existing system (GEHC Discovery XR656 Plus).

•EMD Technologies Epsilon Series generator. (Or generators already on site)



6. **Safety and Effectiveness, comparison to predicate device.** The results of bench and standards testing indicates that the new device is as safe and effective as the predicate device. Risk analysis has been performed.
7. **Substantial Equivalence Chart, Halifax Imaging Kit**

Characteristic	Halifax SR Suite 1.0 K121345	Halifax Imaging Kit Option *Utilizes existing radiography system OR new components.
Intended Use:	This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures.) Not for mammography.	This is a stationary digital x-ray system for general radiography and RSA (Roentgen Stereophotogrammetric Analysis procedures.) Not for mammography.
Generator	Sedecal SHF635RF (Two used)	• Sedecal SHF515C or • Sedecal SHF635RF • Or equivalent Sedecal Generator • EMD Epsilon Generator (Two generators used)
Maximum output	64 kW (Two used)	45-80 kW depending on model selected (Two used) or units already in place.
Stand	Sedecal and Acceleray	Utilizes existing radiography system OR SYFM Stand
Image Acquisition	Digital, dual panels.	Digital, dual panels.
Digital Panel Size	17 x 17	17 x 17 or 14 x 17 or 16 x 16 (Flashpad)
Digital Panel Supplier	Canon CXDI-50RF (Two used, cleared in K092429)	Two of any of the following (all previously cleared): • Agfa DX-D30C or • Canon CXDI-501G or • Canon CXDI-70C or • Canon CXDI-701C or • GE Flashpad (WDR1 Kit) • Any imaging panel with 510(k) clearance which meets Halifax validation criteria.
Digital Resolution	Pixel size 160 × 160 µm Image matrix size 2208 × 2688 pixels Number of pixels Approx. 5.9 million pixels	Agfa DX-D30C 139 µm 7.9 million pixels Canon CXDI-501G 125 µm 9.5 million pixels Canon CXDI-70C 125 µm 9.5 million pixels Canon CXDI-701C 125 µm 9.5 million pixels GE Flashpad 200 µm , 4.1 million pixels
Software	The SR Suite employs the software cleared in K042383, the RSA-CMS. The software was designed specifically to perform Roentgen Stereophotogrammetric Analysis.	Unchanged
Acquisition Software	SR Suite 1.0 employs the acquisition software cleared in K092429 for the digital panel.	Unchanged
Collimator	Ralco R225	Ralco R225 Unchanged
Safety	UL listings and EMC Tested.	UL listed and EMC tested power supply used in the Imaging Kit

Reference to Digital Panel Clearances:

- Agfa DX-D30C K141602
- Canon CXDI-501G K111682)

- Canon CXDI-70C K102012
- Canon CXDI-701C K131106
- GE Flashpad (WDR1 Kit) K102116

8. **Summary of Bench Testing and development activities conducted**:
   The following Risk Management and Risk Analysis documents were created:
   Risk Management Plan - Halifax Imaging Kit
   Risk Management Plan - Imaging Kit Control Module
   Risk Analysis - Imaging Kit Control Module
   Risk Analysis - Halifax Imaging Kit - L-Arm Support
   Fault-Tree Analysis - Imaging Kit Control Module
   Design Verification Testing of the Universal Synchronization Switch was performed in order to verify (a) Proper Board level functionality, firmware and hardware and (b) Proper Enclosure internal wiring assemblies and connections. Finite element analysis was performed on the support structures followed by design verification reviews.
   Verification and Validation reports were executed for the new Imaging Kit, Control Module, and Universal Synchronization Switch.
   Labeling: Installation and User Manuals were developed for the modified portions of the system, and the original labeling was updated according to the FDA Guidance on Cybersecurity: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014.*
   The following reports were prepared documenting bench testing activities:
   Design Verification Test, Universal Synchronization Switch
   Imaging Kit Control Module Verification Report
   Imaging Kit Control Module Validation Test Report
   In addition a Requirements Traceability analysis was performed for the Imaging Kit Control Module.
   The power supply chosen for the Imaging Kit Control Module is UL listed and EMC compliant for medical applications per IEC Standards: IEC 60601-1 and IEC 60601-1-2.
   Every installation undergoes a precision validation test prior to turn over to the customer. "The precision of a Radiostereometric Analysis (RSA) System is affected by the components of the RSA System set-up as well as by the features of the individual joint and implant under examination. To validate a new Halifax Imaging Kit at "[Hospital]" in [City] ([Room details]), [State/Province], [Country], a phantom study was undertaken using a small carbon fibre box. Phantom studies, commonly used for RSA validation [1-12], are a technique used to calculate in vitro precision and accuracy of an RSA System."

9. **Summary of Clinical Testing**: Clinical testing was not required to establish equivalence because all of the new digital receptor panels already have their own 510(k) clearances.

10. **Conclusion**: After analyzing bench testing, standards testing data, and risk analysis it is the conclusion of Halifax Biomedical that the Halifax Imaging Kit Option is as safe and effective as the predicate device, has no significant technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.