DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 10, 2015

ATLAIM Corporation
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K152151
Trade/Device Name: ATAL 9
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 14, 2015
Received: October 16, 2015

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152151

Device Name
ATAL 9

Indications for Use *(Describe)*
The ATAL 9 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic 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
510(k) Number K152151

ATLAIM Corporation
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Anyang-si, Gyeonggi-do, 431-804, Korea
Tel +82-70-4846-8888 FAX +82-2-6455-2905
Date Prepared: November 3, 2015
Contact: Young Kim, President

1. **Identification of the Device:**
   Proprietary-Trade Name: ATAL 9
   Classification Name: Stationary X-ray System
   Common/Usual Name: Digital X-Ray Receptor Panel
   Product Code: MQB
   Device Class/Regulation Number: Class II per regulation 892.1680

2. **Equivalent legally marketed device**: ATAL 8, ATAL 8c, K113812, Atlaim Corporation.
   Classification Name: Stationary X-ray System
   Common/Usual Name: Digital X-Ray Receptor Panel
   Product Code: MQB
   Device Class/Regulation Number: Class II per regulation 892.1680

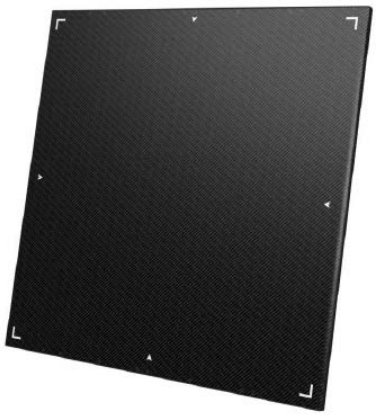
3. **Indications for Use (intended use)** The ATAL 9 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications.

4. **Description of the Device**: The ATAL 9 is a MODIFICATION of our clearance K113812 wherein we have changed panel to a wireless version of the previously cleared panel/software combination. **Going wireless with battery operation are the ONLY modifications.** The available scintillators (CsI or GOS) remain the same. The triggering methods (AED or manual trigger) remain the same. When used with an electrical synchronization circuit the following generators are known to properly synchronize: Sedecal SHF Series and CPI 200 Series.

   The ATAL 9 is a digital radiography system, featuring an integrated flat panel digital detector (FPD). ATAL 9 is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of the modified panel are the same as our previous panel with a Wi-Fi wireless feature added.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate device. Clinical images collected demonstrate equal or better image quality as compared to our predicate.

6. Substantial Equivalence Chart

	ATAL 8 ATAL 8c, K113812	ATAL 9
Intended Use:	Indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications.	UNCHANGED
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	UNCHANGED
Digital Panel		
Pixel Pitch	139 µm	SAME
Limiting Resolution	Over 3 lp/mm	SAME
DQE (CSI)	At 2 lp/mm 27%	At 2 lp/mm 26%
MTF (CSI)	At 2 lp/mm 43%	At 2 lp/mm 42%
A/D Conversion	14 bits	16 bits
Active Area	17 x 17 inch	SAME
Dimensions/ Weights	500(W)×500(L)×25(H)/ 7.8kg	460(W)×461(L)×15(H)/ 2.9kg (2.4kg w/o Battery) (up to 10 hours of battery life)
Pixels	3,072 x 3072 (9.4 M. pixels)	SAME
Software	Outputs a DICOM image.	SAME as K113812
DICOM	Yes	YES
Scintillator	Csl/GOS	UNCHANGED
Interface	Gigabit Ethernet	Wired : Gigabit Ethernet (1000BASE-T) Wireless : IEEE802.11ac, backward compatible
Power source	AC Line	AC Line and/or Rechargeable Lithium Battery (10 hr run time)
Photo		

	ATAL 8 ATAL 8c, K113812	ATAL 9
Standards	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2 as well as IEEE 802.11ac. Meets FCC requirements.

7. Summary of Bench Testing Conducted: IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility. MTF and DQE measurements, Risk Analysis and Software verification were conducted in accordance with FDA guidance documents. As expected the DQE and MTF measurements show minimal differences, and the limiting resolution is the same. The software remains the same as in K113812. Wireless communication testing was performed to verify wireless connectivity. The device was also found to comply with FCC requirements for wireless operation. Bench testing was performed in accordance with the FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

8. Summary of Clinical Testing: Clinical images were acquired and evaluated by a board certified radiologist who concluded the images from the new panel are as good as or better than the images acquired with the predicate panel, as required by the FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices. The core technology of the panel remains the same. The provided clinical data was not used to support a determination of substantial equivalence due to the minor modifications and adequate bench testing data.

9. Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Atlaim that the ATAL 9 (Wireless) is as safe and effective as the predicate device. The Atlaim ATAL 9 has the same intended use as the legally marketed predicate device. Although the ATAL 9 has different technological characteristics, including the addition of wireless technology to the digital image receptor, those differences do not raise different questions of safety and effectiveness from the predicate device. The effects of these differences were adequately documented with bench testing data which showed that the ATAL 9 is substantially equivalent to the predicate device.