Athlos Oy
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

July 22, 2021

Re: K211688
Trade/Device Name: DC-Air™ and Athlos-1 and Athlos-Air
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: July 7, 2021
Received: July 12, 2021

Dear Prithul Bom:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211688

Device Name
DC-Air™, Athlos-1, Athlos-Air

Indications for Use *(Describe)*
DC-Air™, Athlos-1, Athlos-Air are intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw, and oral structures.

DC-Air™, Athlos-1, Athlos-Air are suitable for general populations.

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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K211688

510(k) Summary

In accordance with 21 CFR 807.92, the following summary of information is provided:

1 Submitter

Name:	Athlos Oy
Address:	Klovinpellontie 1-3, 02180 Espoo, FINLAND
Phone:	+358 (0)40 1362566
Fax:	N/A
Primary Contact Person:	Linda Kellberg, Quality Manager, linda.kellberg@athlos.fi
Secondary Contact Person:	Konstantinos Spartiotis, CEO, konstantinos.spartiotis@athlos.fi
Date Prepared:	June 29, 2021

2 Device Classification

Trade Names:	DC-Air™, Athlos-1, Athlos-Air
Common Name:	Intraoral Digital X-ray Sensor
Regulation Number:	21 CFR 872.1800
Classification Name:	Extraoral Source X-ray System
Product Code:	MUH
Submission Type:	510(k)
Regulatory Class:	2
Classification Panel:	Radiology

3 Predicate Device

The following predicate is a legally marketed device:

510(k) Number:	K151926
Clearance Date:	December 14, 2015
Actual Trade Name:	QuickRay HD
Regulation Number:	21 CFR 872.1800
Product Code:	MUH

4 Device Description

The subject device DC-Air™ (also known as Athlos-1 and Athlos-Air) is a wireless intraoral digital X-ray system that comprises of three (3) main components:

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(1) An intraoral X-ray image detector (sensor) with rechargeable battery for capturing X-ray images and which connects to the docking station via a wireless communications protocol (Bluetooth 5.0),
(2) A docking station that acts as the receiver of the data (X-ray image) sent by the detector and which forwards the data to the operator's personal computer (PC) via USB connection. Also, the docking station functions as a charging station of the detector, and
(3) An Imaging Software package.

DC-Air™ digital intraoral sensor:

- Outer measurement: 43.4mm±0.3mm x 29.5mm±0.3mm x 5.4±0.3mm (9.4±0.3mm with battery compartment)
- Active area: 35.1mm x 24.7mm (867 mm^2)
- Weight: 12.2±0.8g

DC-Air™ docking station:

- Outer measurements: 54.2±2.0mm (without antenna), ø 100±2.0mm
- Weight: 200±50g and maximum 400g ballast (user choice)

The three (3) different brand names are for marketing purposes.

The DC-Air™ intraoral sensor features a Size 2 digital X-ray imaging device for dental intraoral diagnosis. The DC-Air™ utilizes Bluetooth (5.0) Low Energy technology to transfer the captured X-ray image from the DC-Air™ sensor to the docking station which further relays it to a connected diagnostics PC. The sensor operates with an integrated battery that can be recharged by placing it on the docking station.

DC-Air™ utilizes Direct Conversion Technology which comprises Silicon as the detector material bump bonded to a full custom ASIC. The sensor features on-board automatic X-ray detection and triggering. The sensor can be used at up to 3m (9f) from the docking station which utilizes a USB2.0 port for "plug-n-play" operation. The sensor also incorporates an image RAM where each X-ray is temporarily stored pending transmission but can be retrieved at any time before the next acquisition.

Before the Athlos' importer in the US sells this device, their technicians discuss the hardware and software that the dentist has, to make sure that their systems are compatible with DC-Air™. The importer offers technical support for this device to ensure proper operation and to answer any questions regarding the function of the device. A means to contact the importer is provided to all end users and in the operator's manual.

The types of X-ray systems that integrate with the DC-Air™ are wall-mounted or wheeled X-ray generators (both AC and DC) with a tube current between 2mA and 15mA inclusive, and with a tube voltage between 50kV and 75kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time. Alternatively,

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the DC-Air™ can be used in conjunction with a portable, handheld X-ray generator with a tube current between 2mA and 10mA inclusive and with a tube voltage 50kV and 75kV inclusive.

The DC-Air™ sensor system cannot act as an X-ray generator controller. All control of X-ray generation is done by controls built into the generator itself. **There is no connection between the subject device and the X-ray generator. The subject device does not control the generator, it is a receiver.**

The DC-Air™ (or Athlos-1 or Athlos-Air) Imaging Software is supported by Windows 7 and 10. The absolute minimum requirements for PC hardware for the sensor and software combination would be an Intel i5 6th generation processor or equivalent. At least 4 GB of RAM, 100GB of hard drive space to accommodate a) the software, b) the space necessary for the repository of images generated by DC-Air™ backup, and c) logging of errors and messages. The PC should have a USB 2.0 Port. The TWAIN interface provided by the DC-Air™ sensor system may also bridge the images to other FDA-cleared imaging and practice management software.

The DC-Air™ intraoral sensor and docking station can also be used with other FDA-cleared imaging software and practice management systems, including Dentrix Ascend Imaging (K151438, cleared July 7, 2015), Apteryx XrayVision (K983111, cleared Nov. 16, 1998), and DEXIS Software (K090431, cleared June 22, 2009). The supported operating systems are Windows 7 and 10. The used PC should meet all requirements (if in excess of the above) of the specific third-party Practice Management Software (PMS) or Imaging Software if installed on the same PC.

Images are captured by the DC-Air™ sensor and transmitted in digital form wirelessly to the docking station and finally via USB connection for display, storage and printing on the PC using Archimed Suite imaging software. This software is brand labeled for Athlos Oy as DC-Air™ (or Athlos-1 or Athlos-Air) and has the same functionality as the software of the predicate device. Archimed Suite complies with the European Directive 93/42/EEC and is CE certified (1575/MMD) by IMQ 0051 Italy.

5 Indications for Use

DC-Air™, Athlos-1, Athlos-Air are intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw, and oral structures.

DC-Air™, Athlos-1, Athlos-Air are suitable for general populations.

6 Intended Use

DC-Air™, Athlos-1, Athlos-Air digital sensor systems are intended for radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure.

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DC-Air™, Athlos-1, Athlos-Air digital sensors are intended to capture an intraoral X-ray image, when exposed to X-rays, for dental diagnostic purposes.

7 Comparison of Technological Characteristics with Predicate

With respect to the 2D intraoral exposures, the proposed DC-Air™ digital sensor system utilizes a Si-CMOS (Direct Conversion) sensor, whereas the predicate QuickRay HD (K151926) utilizes a CMOS (scintillation) sensor. Additionally, DC-Air™ transmits the image via a Bluetooth transceiver, eliminating the wire between the sensor and the PC.

A “Direct Conversion” X-ray imaging sensor is an imaging device that converts X-ray energy directly to electrical signal charge. No intermediate conversion of X-rays to visible light photons is present in the imaging process as opposed to the predicate device which converts X-rays to light and light is converted then to electronic signal. There are several benefits of direct conversion in comparison to the indirect conversion of the predicate device. The sharpness of images produced by DC-Air™ (as quantified by the MTF) is a result of the minimal lateral spread of the signal charge during the image acquisition process. The predicate device first converts X-rays to light which exhibits a higher degree of image blur due to the spread of the visible photons in all directions within the converting scintillator material and inside the fiber optic plate. This spread can be several hundreds of micrometers. In DC-Air™ the X-ray induced signal electrons are driven by an electric field to the signal input node and collected in a very short time limiting lateral charge signal diffusion to a few tens of micrometers.

The principle and design of a direct conversion X-ray imaging sensor is shown and compared to a conventional scintillator-based sensor in the Figure below.

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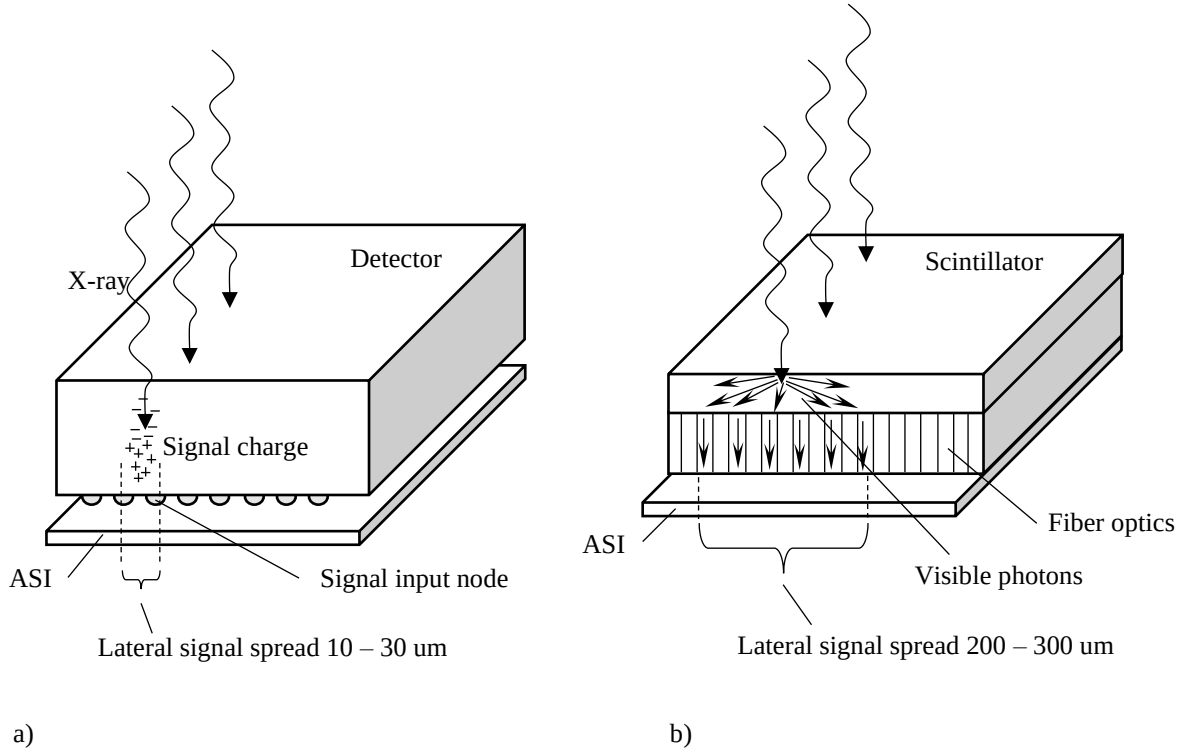

Figure 6-1: Comparison of (a) *a direct DC-Air™ and* (b) *an indirect X-ray imaging sensor*

In DC-Air™ (a) the X-rays are converted directly to charge in the Si semiconductor. The signal charge is driven by an electric field to the signal input node amplifier. A CMOS is connected to the Si detector and is used only as a readout to output the X-ray induced signals. In an indirect sensor (b) the X-rays are first converted to light in the bulk of the scintillator, i.e., visible photons which spread in all directions in the scintillator. The visible photons are then guided by a fiber optic plate to photodiodes, covering part of the pixels on the CMOS, which convert them to electrons. The signal charge is amplified and read out by an ASIC. Therefore, in the predicate device both the scintillator and the CMOS act as part of the detector. The CMOS has a fill factor which means that only a fraction of the pixel is sensitive to incoming light.

The directly converting DC-Air™ wireless intraoral sensor uses depleted crystalline silicon as the X-ray converting semiconductor detector material.

The subject device is using DC-Air™ (or Athlos-1 or Athlos-Air) imaging software which is the brand name for Athlos Oy of the software “Archimed Suite”, a software produced by Digital Imaging. Archimed Suite complies with the European Directive 93/42/EEC and subsequent amendments and additions (CE certification 1575/MMD issued by IMQ 0051, Italy). The predicate uses third party software called Xray Vision which is manufactured by Apteryx in Akron, Ohio (K983111) cleared November 16, 1998.

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Table 6-1: Similarities and differences between the new DC-Air and the predicate QuickRay HD

Feature:	Subject Device: DC-Air	Predicate Device: QuickRay HD	Equivalence:	Differences:
510(k) number:	Not assigned yet	K151926	N/A[1]	N/A
Regulation number:	21 CFR 872.1800	21 CFR 872.1800	Same	None
Classification and product code:	Class 2, MUH	Class 2, MUH	Same	None
Indications for use:	DC-Air™, Athlos-1, Athlos-Air wireless digital sensors are intended to be used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw, and oral structures. DC-Air™, Athlos-1, Athlos-Air are suitable for general populations.	QuickRay HD is used for a radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.	Same	None
Prescription/ over-the-counter use:	Prescription use	Prescription use	Same	None
Size(s):	1280mm^2	Size 1: 600mm^2 (pediatric use), Size 2: 884mm^2 (adults)	Similar	DC-Air comes in 1 size only (Size 2 intraoral x-ray sensor)
Power supply:	Battery-powered	USB-powered (connected to PC or laptop)	Similar	DC-Air sensor is wireless and thus, battery-operated

[1] N/A = Not Applicable

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Feature:	Subject Device: DC-Air	Predicate Device: QuickRay HD	Equivalence:	Differences:
Principles of operation:	X-ray (radiation) >> Si Direct Conversion (convert to electron-hole pairs) >> CMOS (readout) >> Electronics (convert to digital, capture & wireless transmission) >> PC (display image)	X-ray (radiation) >> Indirect Conversion Scintillator (convert to light) >> Fiber optic (filtering) >> CMOS (convert to electron hole pairs & then readout)>> Electronics (convert to digital, capture and wired transmission) >> PC (display image)	Similar	DC-Air uses direct conversion technology
Software – Image Management	DC-Air (and Athlos-1 and Athlos-Air) Imaging Software (package from Digital Imaging, Italy)	Xray Vision (package from Apteryx, USA)	Same	None
Operating system (PC/laptop)	Windows 7, 8, 8.1 and 10	Windows Vista, Windows XP, Windows 7, 8, 8.1 and 10	Similar	DC-Air PC software is not for use with Windows Vista nor Windows XP
Software – Firmware:	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board	Same	None
Sensor technology:	CMOS chip (readout) + Si Direct Conversion	CMOS chip (detection of light + readout) + Optical fiber plate + CSi scintillator	Similar	DC-Air uses direct conversion technology
Matrix dimensions (mm^2):	Active area: 866mm^2	Active area: Size 1: 600mm^2, Size 2: 884mm^2	Similar (size 2)	DC-Air comes in 1 size only (Size 2 intraoral x-ray sensor)
Matrix dimensions (pixels):	1350 x 950	Size 1: 1000 lines X 1500 columns, Size 2: 1300 X 1700	Similar (size 2)	DC-Air comes in 1 size only (Size 2 intraoral x-ray sensor)

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Feature:	Subject Device: DC-Air	Predicate Device: QuickRay HD	Equivalence:	Differences:
Lifespan CMOS:	Min. 50,000 cycles	Min. 100,000 cycles	Similar	Lifespan of CMOS used in DC-Air is comparable to that of the predicate's
Resolution:	Real ≥ 19pl/mm	Real ≥ 20pl/mm	Similar	Resolution of DC-Air is comparable to that of the predicate device
Pixel size:	26 * 26µm^2	20 * 20 µm^2	Similar	Pixel size of DC-Air is slightly larger than that of the predicate device
MTF[2] @ 2lp/mm	85%	60%	Similar	Sharpness of the DC-Air is higher than that of the predicate device on all diagnostic line pair frequencies
MTF @ 5lp/mm	>70%	30% - 45%	Similar	Sharpness of the DC-Air is higher than that of the predicate device on all diagnostic line pair frequencies
MTF @ 10lp/mm	>40%	8% - 25%	Similar	Sharpness of the DC-Air is higher than that of the predicate device on all diagnostic line pair frequencies
DQE:	DQE(0)=4.5% (RQA5) DQE(5)=2.5 % (RQA5) DQE(10)=1.5% (RQA5) DQE(15)=1% (RQA5)	DQE(0)=45% DQE(5)=20% DQE(10)=5% DQE(15)=1%	Similar	DQE of the DC-Air is lower than that of the predicate

[2] MTF = Modulation Transfer Function

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Feature:	Subject Device: DC-Air	Predicate Device: QuickRay HD	Equivalence:	Differences:
Grey levels:	12 bits	14 bits	Similar	Digital scales of DC-Air are less than the predicate device
Sensor board:	Part of control electronics directly integrated on CMOS sensor chip. ADC, triggering, and memory integrated on sensor board.	All control electronics directly integrated on CMOS sensor chip	Similar	ADC, triggering, and memory of the DC-Air are integrated on the sensor board. Predicate does not have on-board memory.
Sensor shell:	Specific shape design. Material is Polyphensylsulfone, flammability V-0 (UL file No. E36098).	Specific shape design. Material is ABS and the flammability is HB if YK-94 (UL File No. 49895).	Same	None
Sensor housing:	IP67 protected IP64 protected	IP67 protected	Same	None
Connection to PC:	USB 2.0 (via docking station)	USB 2.0 High-Speed	Same	None
Operating temperature:	+10°C to 35°C	0°C to 35°C	Same	None
Sensor input voltage and current:	3.5 to 4.15 V (battery), 9.7 mA	5V (via USB connection), 0.15A Max	Similar	DC-Air sensor uses lower voltage and current
Standards of conformity:	IEC 60601-1 (Electrical safety) IEC 60601-1-2 (EMC) IEC 62220-1-1 (Performance) IEC 60529 (IP Code)	IEC 60601-1 (Electrical) IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)	Same	None

8 Performance Data

X-ray images taken using the DC-Air™ were examined by doctors Robert Sachs D.D.S., John M. Steinberg D.D.S., and Steven R. Gluck D.D.S. and found to be diagnostically relevant and reliable.

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9 Biocompatibility

Biocompatible testing for the subject device DC-Air™ is not warranted because there are no direct or indirect patient-contacting components in the device. DC-Air™ sensor is covered with a single-use protective barrier prior to each use like its predicate QuickRay HD (K151926).

10 Electrical Safety and EMC

The subject device DC-Air™ has been tested for electrical safety and EMC.

The DC-Air™ sensor and docking station conform to electrical and safety standard IEC 60601-1 Medical Electrical Equipment - Part I: General requirements for basic safety and essential performance.

The DC-Air™ sensor and docking station conform to electrical and safety standard IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility.

The DC-Air™ sensor and docking station conform to regulation FCC CFR 47 Part 15 B.

11 Software Verification and Validation Testing

DC-Air™ sensor and docking station electronics contain firmware. Additionally, DC-Air™ uses imaging software provided by Digital Imaging, Italy. Therefore, only firmware documentation for the subject device is included in this submission.

12 Bench Testing

Bench tests for subject device DC-Air™ were performed in conformance with standard IEC 62220-1-1 Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging and standard IEC 60529 Degrees of Protection Provided by Enclosures - IP Codes.

13 Conclusions

The subject DC-Air™ and its predicate device QuickRay HD (K151926) have the same intended use and similar technological features. DC-Air™ and QuickRay HD are similar in terms of operation and sensor technology and they use similar imaging software. QuickRay HD is connected to the PC via a USB cable. DC-Air™ sensor is intended for wireless operation. However, USB connection between the DC-Air™ sensor and the PC is enabled via DC-Air™ docking station.

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The conclusion is that the subject device DC-Air™ is as safe and effective as the predicate QuickRay HD and these devices are identical in structure and use. The software packages of the subject device and the predicate are different. The subject device PC software has been FDA cleared with other similar devices (DEEP View by Trident s.r.l. as part of K160386).

Athlos Oy believes that the subject device DC-Air™ and its predicate QuickRay HD are similar.