K101285

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. **Date Summary Prepared:**
   May 5, 2010

2. **Submitter's Identification:**
   Air Techniques, Inc.
   1295 Walt Whitman Road
   Melville, NY, 11747

   AUG 03 2010

   Contact: Pablo Martinez
   Tel: 516-214-5541
   Email: pmartinez@airtechniques.com

3. **Device Name:**

Trade /Proprietary Name:	ScanX D5000 Series Scanner Product codes: D5000-F, D5000-FB, D5000-FVB, D5000-Q, D5000-QB
Common Name:	Scanner for Computed Radiography
Classification name:	Solid State X-Ray Imaging System, 892.1630

4. **Predicate Device Information:**
   The legally marketed devices to which equivalence is being claimed are:

   ScanX 10- 510K 031198
   Air Techniques, Inc., Melville, New York USA

   ScanX Scanner, 510K 013893
   Air Techniques, Inc., Melville, New York USA

   Portable X-Ray System : AnyRay – 510K 081899
   Giheung-Gu, Yongin-Si, Gyeonggi-Do, Korea

5. **Device Description:**
   The ScanX D5000 series scanner is a device that reads photostimulable phosphor plates that have been exposed in place of x-ray film and allows those images to be displayed on a personal computer display.

6. **Intended Use/Indications for use:**
   The ScanX D5000 series scanners, with and without battery option are devices that read photostimulable phosphor plates that have been exposed in place of x-ray film and allow those images to be displayed on a personal computer display and stored for later recovery in a computer's memory. It will be used by

physicians, dentists, veterinarians, and authorized medical auxiliary personnel for this purpose.

7. **Basis for Determining Substantial Equivalence:**

The ScanX D5000 series scanners are identical in concept, design, and function to the ScanX 10 Medical Imaging System and the Dental ScanX Scanner manufactured by Air Techniques, Inc. These medical and dental units currently in commercial distribution were cleared under K031198 and K013893. The ScanX D5000 series scanners consist of models provided with and without an internal battery that can be used in the medical, dental, and veterinary markets.

The rechargeable lithium battery used in the ScanX D5000-FB, D5000-FVB, and D5000-QB battery operated scanners is equivalent to a predicate Portable X-Ray System "Any Ray", 510(K) number K081899. The indications for use and basic overall specifications, operational characteristics, and materials used for the rechargeable battery are substantially equivalent.

The ScanX D5000 series scanners with battery option will be marketed under our All-Pro Imaging brand name.

Characteristic	**Air Techniques ScanX D5000 with Battery (modified device)**	**Air Techniques ScanX 12 (formerly ScanX 10) (predicate device)**
Mechanical design	same as predicate	The exposed plates are scanned in two orthogonal directions using a laser and a wavelength of approximately 635 nm
Mechanical enclosure	Metal and plastic enclosure	Metal enclosure
Electrical design	same as predicate	390 (approximately) nm light emitted from the lasered plate is collected by a photo multiplier tube and formed into an image that may be viewed on a computer monitor and stored for later recovery in a PC-computer memory.
Erasing the residual image following scanning for plate reuse.	Upon completion of the scanning, the PSP passes through the ILE (In-Line Erase) a row of Red LEDs which erases the image on the PSP.	Upon exit from the scanner, the plate is manually inserted into an external plate eraser (non-medical device) where it is exposed to high intensity light for a controlled time.
Viewing the image	Same as predicate device	The scanned image is displayed using a computer and user software (not part of the scanner system) which accommodates image storage, retrieval and manipulation.

Plate input and exit heights	Accepts 14x17 inch plates and smaller plates	Accepts 10 x12 inch plates and smaller plates
Intended use	Same as predicate device, and added the use of intraoral PSP plates used by dentists and veterinarians.	System is intended to be used with extraoral and medical imaging plates by medical professionals.
Manufacturer	Same as predicate	Air Techniques, Inc., doing business as All-Pro Imaging
Body size and weight	15 ½"W x 17 ½"L x 13.75"H 45 lbs.	14"W x 14"L x 28"H 55 lbs.
Software	New PC Boards and reconfigured firmware, mitigated thru product and process validation located in Exhibit 7	PCB and controller boards programmed with software and firmware.
User interface	Same as predicate	Licensed and trained dentist and medical technicians
Energy Source AC	100 to 240VAC, 50/60 Hz, 2.5A maximum	100 to 240VAC, 50/60 Hz, 1.5A minimum
Energy Source DC	Rechargeable 26.4V DC Lithium ion 8 cell battery pack	Not Applicable
Battery Rating	2300 mAH	Not Applicable
Battery Safety & Performance Testing	Battery pack tested to UL 2054. Battery cells tested to UL 1642	Not Applicable
Electrical safety standards	Same as predicate and UL2054	UL60601-1 (safety)
EMI Safety Testing	IEC 61000	IEC 61000
Performance standards	Same as predicate	IEC EMC testing /EN 60601-1-2
Biocompatibility	Not applicable (no patient contact)	Not applicable (no patient contact)
Sterility	Not applicable	Not applicable
Shelf Life	Not applicable	Not applicable

8. **Conclusions:**
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Air Techniques, Inc. concludes that the ScanX D5000 Series scanners are safe and effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Pablo Martinez
Director of Compliance & Regulatory Affairs
Air Techniques, Inc.
1295 Walt Whitman Road
MELVILLE NY 11747-3062

AUG 23 2013

Re: K101289
Trade/Device Name: ScanX D5000 Series, Models: D5000-F, D5000-FB, D5000-FVB, D5000-Q and D5000-QB
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 5, 2010
Received: May 7, 2010

Dear Mr. Martinez:

This letter corrects our substantially equivalent letter of August 8, 2010.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

AUG 03 2010

Indications for Use

510(k) Number (if known): K101289 K101289

Device Name: ScanX D5000 Series
Product Codes: D5000-F, D5000-FB, D5000-FVB, D5000-Q and D5000-QB

Indications for Use:

The ScanX D5000 series scanners, with and without battery option are devices that read photostimulable phosphor plates that have been exposed in place of x-ray film and allow those images to be displayed on a personal computer display and stored for later recovery in a computer's memory. It will be used by physicians, dentists, veterinarians, and authorized medical auxiliary personnel for this purpose. These scanners are not intended to be used for mammographic images.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101289