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Tab 4

510(k) Summary

JUN 23 2008

NOMAD Pro Handheld X-ray System
30 May 2008

1. **Company:**

Name: Aribex, Inc.
Address: 744 South 400 East
Orem, UT 84651

Official Correspondent: D. Clark Turner, PhD, CEO

Telephone No: 801-226-5522
FAX No: 801-434-7233

2. **Proprietary – Trade Name:** NOMAD Pro X-ray System
Classification Name: Extraoral source X-ray system (per 21CFR section 872.1800)
Common/Usual Name: Handheld Dental X-ray System

Predicate Device: Port-X II Portable X-ray System, 510(k) # K0063121, manufactured by Genoray, and the NOMAD Dental X-ray System, 510(k) #K051795, manufactured by Aribex. Literature included at Tab 12.

3. **Description:** **NOMAD Pro** is a handheld dental X-ray system that operates on 22.2 V DC supplied by a rechargeable Lithium Polymer battery pack enclosed in a Handset. The X-ray tubehead, X-ray controls, and power source are assembled into a single hand-held enclosure. The package includes a spare battery Handset, a Charging Cradle, an AC-to DC Power Supply, and a permanently attached Backscatter Shield.

4. **Intended Use:** The **NOMAD Pro** X-ray System is intended to be used by trained dentists and dental technicians as an extraoral X-ray source for producing diagnostic X-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

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5. **Comparison with predicate devices:**

Feature	Genoray Port-X II K063121	NOMAD Dental Intraoral X-ray Source K051795	NOMAD Pro Intraoral X-ray Source
INTENDED USE:	All three systems are intended as extraoral X-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.		
MECHANICAL:			
Size: Body	7.8" x 5.8" x 3.7"	13"L x 11.5"H x 5.5"W	10.5"L x 12"H (including shield) x 5.25"W
Weight	5.2 lbs	8.5 lbs.	5.3 lbs.
Source to skin distance	10 cm	20 cm	21 cm
Cone diameter	7 cm	6 cm	6 cm
User Interface	Up-down buttons for exposure time selection, with timer display. Additionally, several user-selectable preset times with patient size and tooth selection icons on an LCD display.	Up-down buttons for exposure time selection, with timer display.	Up-down buttons for exposure time selection, with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display.
Backscatter radiation protection	None	6.75" dia. Pb-filled acrylic plastic scatter shield	6.75" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Exposure button at x-ray control panel	Trigger on tubehead assembly and Start button on control panel	Trigger on Handset
Tubehead mounting	Handheld, or on a tripod	Handheld	Handheld
ELECTRICAL:			
Energy Source	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 14.4 V DC NiCd battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
Exposure Time	0.01 – 2.0 seconds in 46 steps	0.01 – 0.99 seconds in 0.01 increments	0.02 – 1.00 seconds in 0.01 increments
Timer Accuracy	±(10% + 1ms)	±(10% + 1ms)	±(10% + 1ms)
mA	2 mA fixed	2.3 mA fixed	2.5 mA fixed
kVp	60 kV fixed	60 kVp fixed	60 kVp fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	(not available)	1:60	1:60
Electrical Safety Standards	EN60601-1	IEC60601-1, UL60601-1, EN60601-1	IEC60601-1, EN60601-1
EMI Standards	EN60601-1-2	IEC60601-1-2	EN60601-1-2
X-RAY PERFORMANCE:			
Performance Standard	EN60601-1-3 EN60601-2-7 EN60601-2-28 EN60601-2-32	21 CFR 1020.30, 1020.31 IEC60601-1-3 IEC60601-2-7	21 CFR 1020.30, 1020.31 IEC60601-1-3 IEC60601-2-7

6. **Conclusion:** In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, Aribex, Inc. concludes that the NOMAD Pro Portable X-ray System is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2008

Aribex, Inc.
c/o Mr. Morten Simon Christensen
Staff Engineer/Reviewer
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K081664
Trade/Device Name: NOMAD Pro X-ray System
Regulation Number: 21 CFR §872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: June 10, 2008
Received: June 13, 2008

Dear Mr. Christensen:

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, 1796, 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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number: K 081664

Device Name: NOMAD Pro X-ray System

Indications for Use: The NOMAD Pro X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081664

Prescription Use X OR Over-The-Counter Use ___
(per 21CFR801.109)