K111167

AUG 18 2011

VELOPEX INTERNATIONAL
105 East 17th Street
St. Cloud, FL 34769
1-888-835-6739

Date: April 21, 2011

510(k) Holder: Velopex International Inc
Establishment Registration # 3003697084
Device Name: ExtraXtender Film Processor, Sprint Film Processor
Contact: Anthony Urella
Phone: 407-957-3900
Fax: 407-957-3927
Email: tony@velopexusa.com

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510 (k) Summary

Device Name: ExtraXtender Film Processor
Sprint Film Processor

- Trade Name: Xtender Film Processor, Sprint Film Processor
- Common Name: Automatic Film processor
- Classification name: Processor, Radiographic-Film, Automatic
- Device Class 2
- Regulation Number: 892.1900

Legally marketed device to which we are claiming equivalence:

- Velopex IntraX Film Processor #K093503
- Air Techniques Inc. (Registered Establishment # 2428225) A/T 2000 Automatic Film Processor
- Dent-X Co., Model 410 Dental X-Ray Film Processor #K874118
- Air Techniques Inc. (Registered Establishment # 2428225) Peri-Pro Film Processor
- Air Techniques Inc. (Registered Establishment # 2428225) All-Pro 2010 Film Processor
- Air Techniques Inc. (Registered Establishment # 2428225) All-Pro 100 Plus Film Processor

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

Velopex International Inc.
% Mr. Anthony Urella
Vice President, Sales & Marketing
105 East 17th Street
SAINT CLOUD FL 34769

AUG 18 2011

Re: K111167
Trade/Device Name: ExtraXtender Film Processor, Sprint Film Processor
Regulation Number: 21 CFR 892.1900
Regulation Name: Automatic radiographic film processor
Regulatory Class: II
Product Code: IXW
Dated: April 21, 2011
Received: June 6, 2011

Dear Mr. Urella:

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,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111167

Device Name: ExtraXtender Film Processor

Indications for Use:

The ExtraXtender Film Processor is an automatic filmprocessor used by dental offices to develop X-ray films. The ExtraXtender processes all film sizes of intra-oral and extra oral film. High quality archivable radiographs are delivered dry in 5 minutes. Films may be viewed wet after 2½ minutes

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

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

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

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111167

Indications for Use Form

510(k) Number (if known): K111167

Device Name: Sprint Film Processor

Indications for Use:

The Sprint Film Processor is an automatic film processor used by dental offices to develop x-ray films. The Sprint Film Processor processes all sizes of intra-oral film. Films may be viewed wet after 2 1/2 minutes.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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