MAR - 6 2012

510(k) Summary for the VIVI Ergon-X HF

This 510(k) Summary is submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: VIVI S.r.l. is located at:
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Summary Preparation Date: 11,04,2011

2. Names

Device Name: VIVI Ergon-X HF
Common Name: Unit, x-ray, extraoral with timer
Product Code: EHD
Classification: II

3. Predicate Devices

The VIVI Ergon-X HF is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number
Sirona Dental Systems GmbH	HELIODENT Plus	K083344
Villa Sistemi	ENDOS DC	K030634
Progeny Inc	PREVA	K043092

VIVI Ergon-X HF and its predicate devices are indicated for the same intended use and have equivalent design solutions .

They have the same operating principle (X-ray tube) and equivalent technical characteristics. Moreover, a comparative test was performed with the predicate device Endos DC (K030634) and this test demonstrated that the output to the patient is equivalent for both VIVI Ergon-X HF and Endos DC (K030634).

4. Device Description

VIVI Ergon-X HF is a device made up of a mobile and articulate double support arm. At the opposite ends of the arm are located respectively:

- a central unit equipped with wall plate, extension and radio control device. This unit is the interface on which the control panel is placed;
- the tube head with X-Ray Tube.

5. Indications for Use

Ergon-X-HF is an extraoral X-ray source system intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaws, and oral structures.

6. Performance Data

VIVI Ergon-X HF device has been developed and tested according to the following international standards:

- IEC 60601-1 - Medical Electrical Equipment Part.1: General requirements for safety. 1: Collateral standard: safety requirements for Medical Electrical Systems. *FDA Recognition number 5-4*
- IEC 60601-1-2 Medical Electrical Equipment Part.1: General requirements for safety. 2-Collateral standard: electromagnetic compatibility – requirements and tests. *FDA Recognition number 5-28*
- IEC 60601-1-3 Medical Electrical Equipment - Part.1: General requirements for safety. 3: Collateral standard: general requirements for radiation protection in diagnostic X-ray equipment. *FDA Recognition number 12-199*
- IEC 60601-2-7 Medical Electrical Equipment Part.2-7: particular requirements for high voltage generators safety in diagnostic X-ray equipment. *FDA Recognition number 12-34*
- IEC 60601-2-28 Medical Electrical Equipment Part.2: particular requirements for safety of X-ray generators assembled in diagnostic X-ray equipment. *FDA Recognition number 12-126*
- IEC 62304 , Medical device software - Software life cycle processes. *FDA Recognition number 13-8*
- IEC 60601-1-4, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. *FDA Recognition number 5-41*
- ISO 14971 Medical Devices - Application of risk management to medical devices. *FDA Recognition number 5-40*

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

VIVI S.r.l.
% Mr. Guido Bonapace
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Re: K120318
Trade/Device Name: Ergon-X HF
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD
Dated: January 4, 2012
Received: February 1, 2012

Dear Mr. Bonapace:

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

Indications for Use

510(k) Number (if known): K120318

Device Name: ***Ergon-X HF***

Indications for Use:

Ergon-X-HF is an extraoral X-ray source system intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaws, and oral structures.

Prescription Use ___X___ (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 Device Evaluation (ODE)

Mary S Pastel

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

510K K120318