JUN 18 1999

K991310

VILLA SISTEMI MEDICALI

Annex 1 - 510 (k) SUMMARY

510(k) summary for Explor-X 70

Identification

Applicant	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan- Italy
Contact Person	dr. Francesco Attuati
Telephone (applicant)	+ 39 2 488591
Official Correspondent	Chicago X-Ray Systems, Inc. Wheeling, IL 60090
Contact Person	Al SOSA - President
Telephone (contact person)	847 - 459 3889
Manufacturing site	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan - Italy

Trade name: Explor-X 70
Common name: Explor-X 70 with AP Time X timer
Classification name: according to 21 CFR 872-1800, Explor-X 70 device is in **Class II**.
Substantial equivalent device: the proposed equipment is defined as Substantially Equivalent (SE) to the *Explor-X 70 with Diamatic AP timer.* This assumption is based on the comparison table contained on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1999

Villa Sistemi Medicali S.P.A.
C/o Chicago X-Ray Systems, Inc.
Attn: Al Sosa
251 E. Dundee Road
Wheeling, IL 60090

Re: 510(k) 991310
Trade Name: Explor-X-70 with AP Time X timer
Dated: February 23, 1999
Received: April 16, 1999
Classification: II
21CFR 872.1800
Product Code: 90 EHD

Dear Mr.Sosa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CC: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

510(k) NUMBER (IF KNOWN): K991310
DEVICE NAME: EXPLOR X 70 AP TIME X
INDICATIONS FOR USE:

The Explor X 70 AP TIME X (the Explor X 70 with the AP TIME X timer) is intended for the dental radiographic examination and diagnosis of deseases related to the anatomical structures of the teeth. Such a device makes use of an extra oral source x-ray system commonly referred to as intraoral x-ray equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991310