K984524

JAN 14 1999

VILLA SISTEMI MEDICALI

Annex 1 - 510 (k) SUMMARY

510(k) summary for Aztech 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
Initial distributor in the US	The Aztech Group, Inc. 1401 Walnut Street - suite 565 Boulder - Colorado 80302 Registration Number: 1722809
Contact Person	Robert Padgett - President
Manufacturing site	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan - Italy

Trade name: Aztech 70
Common name: Aztech 70 with VCA timer
Classification name: according to 21 CFR 872-1800, Aztech 70 device is in **Class II**.
Substantial equivalent device: the proposed equipment is defined as Substantially Equivalent (SE) to the Aztech 65 with CCD timer (K950667). This assumption is based on the comparison table contained on the following page.

	Aztech 65 with CCD Timer (K950667)	**Aztech 70 with VCA Timer**
Intended use	extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth	extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth
High Voltage value	65 kV_p	70 kV_p
Tube current	8 mA	8 mA
Tube insert	CEI OCX 70-G	CEI OCX 70-G
H.V. type:	Single phase, self rectifying	Single phase, self rectifying
X-Ray exposure time control	Microprocessor Controlled	Microprocessor Controlled
Compensation of Line Voltage Fluctuations	Yes, automatically by software algorithm	Yes, automatically by software algorithm
Safety features	Dead man command	Improved controls, with feedback sensors Dead man command Safety backup timer (HW)
Signaling devices	Acoustic and visual signal	Acoustic and visual signal Optional remote signaling

The main differences between the proposed equipment and the substantially equivalent one are listed in the following points:

- the application of line voltage to the tubehead is microprocessor controlled
- the ON/OFF switching of the main is controlled through-out the complete cycle
- the user is requested to "enable" the emission by pushing the specific button; this feature, that can be selected by the service engineer, is particularly useful for the remote activation.
- the timer is ready to accept an optional remote signaling of X-Ray emission
- a safety back up timer, capable of inhibitin X-ray emission, independent from the microprocessor control, is provided in order to increase safety.

Aztech 70 description

Aztech 70 is a Dental X-Ray generator; its primary use is for intra oral image receptor radiology. with a peak voltage of 70 kV_p and a tube current of 8 mA. The soft X-Ray are filtered by 2 mm eq. of Al.

The high voltage generator is enclosed in a plastic cover, with an apparently cylindrical aspect. The beam limiting device is formed by a circular cone with a maximum diameter of 6 cm.
The tubehead is mounted on a oval shaped scissors arm, spring balanced. The scissors arm has a length of about 60 cm for each arm. The arm is mounted on an extension arm, that on the standard version has a length of 90 cm: optional configurations are available using extension arm of different lengths (75 and 60 cm).
The unit is marketed as a wall mount permanent equipment.
The electronic control of the VCA timer offers operator the possibility to select between automatic and manual selection of exposure times.
In the automatic mode, selected exposure times according to the tooth. patient type (adult or child) and patient size to be filmed can be selected.
With the manual mode of the VCA timer, the operator has the possibility to choose exposure times in steps ranging from 0.02 up to 3.2 seconds in discrete step increments.
The exposure time is displayed on the timer main box by a three digit LEDs display, both for automatic and manual selection. This display is also used to show error codes, to inform the operator about the various possible faults.
The microprocessor has also the job to compensate the line voltage fluctuations by changing the exposure time. This feature is accomplished by a mathematical algorithm, with a non linear function.
X-Ray exposures are signaled by both acoustic and optical devices.

Indication for use.

The indication for use of the Aztech 70 is**: extra oral source X-ray system** for dental radiographic examination and diagnosis of diseases of the teeth..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Al Sosa
Official Correspondent
The Aztech Groups, Inc.
1401 Walnut Street, Suite 565
Boulder, Colorado 80302

Re: K984524
Aztech 70
Dated: December 9, 1998
Received: December 21, 1998
Regulatory class: II
21 CFR 872.1800/Procode: 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

510 (K) NUMBER (IF KNOWN): K984524

DEVICE NAME: AZTECH 70

INDICATIONS FOR USE:

The Aztech 70 is intended for extra oral source X-ray system for dental radiographic examination and diagnosis of deseases of the teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984524