K03 0185

MAR 11 2003

Appendix 1 - 510 (k) SUMMARY

510(k) summary

Identification

Applicant	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan- Italy Registration Number: 8021091
Contact Person	dr. Roberto Daglio – QA Director
Telephone (applicant)	+ 39 02 48859233
Designated Agent in the US	Andrew Hryndza Del Medical 11550 West King Street Franklin Park Illinois 60131 Tel. 847-288-7000
Manufacturing site	Villa Sistemi Medicali S.p.A. Via delle Azalee 3, 20090 BUCCINASCO - Milan - Italy

Trade name: ENDOS AC – ENDOS ACP
Common name: ENDOS AC – ENDOS ACP intraoral system
Classification name: according to 21 CFR 872-1800, ENDOS AC/ACP is in **Class II**.
Substantial equivalent device: the ENDOS AC - Endos ACP is defined as Substantially Equivalent (SE) to the AZTECH 70 model manufactured by Villa Sistemi Medicali SpA. The predicate device has been approved by FDA and has 510(k) approval number K984524

The following table compares the ENDOS AC- ENDOS ACP with the predicate device

	ENDOS AC-ACP	**Aztech 70**
Intended use	extra oral source X-ray system for dental radiographic examination of the teeth	extra oral source X-ray system for dental radiographic examination of the teeth
High Voltage value	70 kV	70 kV
Tube current	8 mA	8 mA
X-ray Tube insert	CEI OCX 70-G	CEI OCX 70-G
Focal spot size	0.8 mm (IEC 336)	0.8 mm (IEC 336)
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
Total filtration	> 2.0 mm Al	> 2.0 mm Al
HVL	> 1.5 mm Al	> 1.5 mm Al
X-Ray exposure time control	Automatic – pre-programmed in the ACP model; manual in the AC model Microprocessor Controlled	Automatic – pre-programmed Microprocessor Controlled
X-Ray exposure timing	0.020 sec to 3.2 sec	0.040 sec to 3.2 sec
Electrical characteristics	120 V +/- 10% 7.6 impulsive A max	120 V +/- 10% 7.6 impulsive A max
Focus film distance	> 20 cm	> 20 cm
Leakage radiation	< 25 mR/h at 1 meter from focus	< 25 mR/h at 1 meter from focus
X-ray beam dimension at 20cm	< 6cm	< 6cm
Safety features	Dead man command	Dead man command
Signaling devices	Acustic and visual signal	Acustic and visual signal

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2003

Villa Sistemi Medicali, S.p.A.
% Mr. Andrew Hryndza
Del Medical
11550 West King Street
FRANKLIN PARK IL 60131

Re: K030185
Trade/Device Name: Endos AC/ACP
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 76 EHD
Dated: January 10, 2003
Received: January 21, 2003

Dear Mr. Hryndza:

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 either class II (Special Controls) or class III (PMA), it may be subject to 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

K03 0185

Indication for use.

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

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030185