VILLA
SISTEMI
MEDICALI

K002432

SEP 01 2000

Appendix 1 - 510 (k) SUMMARY

510(k) summary for STRATO X

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	Jeff Moeller Gendex Del 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: STRATO X
Common name: STRATO X panoramic device
Classification name: according to 21 CFR 872-1800, STRATO X is in **Class II**.
Substantial equivalent device: the STRATO X is defined as Substantially Equivalent (SE) to the Instrumentarium OC/OP 100 device, manufactured by Instrumentarium Imaging and cleared by FDA with K973642

The following table compares the STRATO X and the predicate device

	STRATO X	**INSTRUMENTARIUM OP 100 - OC 100**
Intended use	extra oral source X-ray system for dental radiographic examination of the teeth and specifically for panoramic examinations, TMJ studies, Implantology, Cephalometry	extra oral source X-ray system for dental radiographic examination of the teeth and specifically for panoramic examinations, TMJ studies, Implantology, Cephalometry
High Voltage value	50 – 80 kV_p	57- 85 kV_p
Tube current	4-12 mA	2-16 mA
Focal spot size	0.5 mm (IEC 336)	0.5 mm (IEC 336)
Total filtration	2.5 mm Al	2.5 mm Al
H.V. generator:	High frequency	High frequency
X-Ray exposure time control	Automatic – pre-programmed Microprocessor Controlled	Automatic – pre-programmed Microprocessor Controlled
Imaging procedures	Panoramic TMJ Sinus Cephalometric Linear tomography	Panoramic TMJ Sinus Cephalometric Linear tomography
X-Ray exposure timing	15 sec in panoramic 0.2 –2 sec in Ceph	8- 17.6 sec in panoramic 0.1- 3.2 sec in Ceph
Electrical characteristics	120 V 18 A max	110 V 1.65 KVA max
Positioning lights	class II laser	Tungsten halogen and class II laser
Panoramic cassette	Flat 15x30	Flat 15x30
Cephalostat cassette	Flat 18x24 and 24x30	Flat 18x24 and 24x30
Focus film distance	512 mm	485 mm
Dimensions	2320x1900x1300	2345x1900x1000

Indication for use.

The indication for use of the Strato X is: **extra oral source X-ray system** for dental radiographic examination of the teeth, specifically for panoramic examinations and Implantology and for TMJ studies and Cephalometry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 01 2000

Villa Sistemi Medicali S.p.A.
c/o Jeffrey N. Moeller, R.T
Director, Quality and Regulatory Affairs
Gendex DEL Medical Systems Group
11550 West King Street
Franklin Park, IL 60131

Re: K002432
STRATO-X
Dated: August 4, 2000
Received: August 8, 2000
Regulatory Class: II
21 CRF 872.1800/Procode: 90 EHD

Dear Mr. Moeller:

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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known):_____

Device Name:_____

Indications For Use:

Device Name: **STRATO X**

The indication for use of the Strato X is: **extra oral source X-ray system** for dental radiographic examination of the teeth, specifically for panoramic examinations and Implantology and for TMJ studies and Cephalometry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002432

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)