

K977968

# CHICAGO X-RAY SYSTEMS INC



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OCT -- 8 1997

510 (k) SUMMARY FOR

Product name: ROTOGRAPH PLUS

This product is manufactured by the Villa Sistemi Medicali company of Milan, Italy and is classified as a class II device. It is intended to be used as a dental extra oral x-ray device for the panoramic and cephalometric examination of the human anatomy as it applies to dentistry.

This product is manufactured under the guidelines of the FDA/DHHS performance standards as it applies to radiation emitting devices and 21 CFR Subchapter J and the International Standard IEC 601.1 and 601.2.7. This product is substantially equivalent to the Belmont X-Caliber unit as marketed in the United States. The manufacturer further warrants that this device is safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 8 1997

Al Sosa  
President  
Chicago X-Ray System Inc.  
219 Mayer Avenue  
Wheeling, IL 60090

Re: K972968  
Rotograph Plus System Software  
Dated: August 8, 1997  
Received: August 11, 1997  
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 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 requirement, 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/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Friday, August 08, 1997

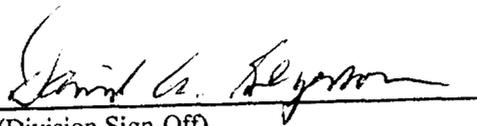
510 (K) Number ( if known): \_\_\_\_\_

Device name: ROTOGRAPH PLUS

## INDICATIONS FOR USE:

The Rotograph Plus as manufactured by Villa Sistemi Medicali S.p.A of Milan, Italy is intended to be used as an extra oral radiological device for the examination of the human dentition and related anatomy as well as craniostatic examinations. They are to be used for Panoramic and Cephalometric Radiology as it is applied to dental diagnosis in dentistry.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972968

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)