K974877

MAR 27 1998

510 (k) Summary Statement for the Soredex Cranex Tome Tomographic, Radiographic System

I General Information

Submitter: Orion Corporation Soredex
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Summary Preparation Date: December 19, 1997

Names

Proprietary Name: Cranex Tome or Cranex Tome Ceph

Common or Usual Name: Tomographic X-ray system

Classification Name: System, Tomographic, Radiographic 90 IZF

III Substantial Equivalent Devices

Scanora (K884650) marketed by Orion Corporation Soredex, Tomographic functions
Oralix Pan DC III Ceph (or Cranex 3 Ceph) (K880982) marketed by Orion Corporation Soredex , cephalometric functions

IV Product Description

Cranex Tome Ceph is a high frequency Tomographic, Radiographic system capable of producing dental panoramic and tomographic images, TMJ (TemporoMandibular Joint) tomographic images and cephalometric images. It is available in two models with (Cranex Tome Ceph) and without (Cranex Tome) the cephalometric option. The Cranex TOME uses the principle of autotomography with a spiral blurring movement. This movement, which is similar to the movement used by the Soredex SCANORA®, is achieved by tilting and rotating the C-arm at the same time.

The Cranex Tome comprises of

- moving column
- C-arm
- An adjustable two-position chin support is used to carry out all exposure procedures.
- Four-point head support and bite-block system
- A large adjustable mirror
- The patient positioning lights
- control panel
- graphical display
- wide range of x-ray programs for mandible, maxilla, temporomandibular joint, sinus, and cephalometric exposures.
- high-frequency generator
-15x30 cm panoramic cassette for paroramic and tomographic imaging

And the following with the cephalometric unit

- Soft tissue filter adjustment with LED positioning indicators
- selectable magnification ratio and a rotatable head support with positioning stops every 45 degrees.
-The system software makes it impossible to take an exposure if the cephalometric cassette is the wrong size or incorrectly positioned.
-Accepts 18x24, 8"x10" or 24x30 cm cephalometric cassettes
-The cephalometric arm can be mounted on either the left- or the right-hand side of the unit
-An cephalometric kit is available so that Cranex TOME can be upgraded to a Cranex TOME Ceph .

V Inteded Use of the Device

The Cranex Tome Ceph is intended for producing x-ray images of dentistry, TMJ and skull.
The Cranex Tome is intended for producing x-ray images of dentistry and TMJ.

VI Indications for Use/Rationale for Substantial Equivalence

Cranex Tome Ceph, Tomographic x-ray system is used as an extra-oral source for x-rays in dental radiography.

It has similar instructions for use and installation, used materials, design, mode of x-ray generation (DC), operational and functional features as the substantial equivalent devices. It does not have all the different imaging programs of Scanora , however a substantial portion of those. Patient supporting, imaging programs and technique factor selection in cephalometric imaging is similar to Oralix Pan DC III Ceph (or Cranex 3 Ceph).

VII Summary of technological charasteristics

Cranex Tome Ceph is
- a high-frequency DC X-ray equipment
- imaging programs for panoramic and tomographic examinations of the dentistry
- imaging programs for tomographic examinations of the TMJ
- imaging programs for cephalometric examinations of the skull.

VIII Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:
- clinical tests
- software verification, validation and certification procedures
- risk analysis
- risk management file

All the above items and evaluations lead to the conclution that Cranex Tome and Cranex Tome Ceph are safe and effective when the unit is used as labeled.

IX Conclution

Crane Tome Ceph Tomographic, Radiographic system is substantially equivalent to the predicate devices : Scanora and Oralix DC III Ceph (or Cranex 3 Ceph).
The unit has similar design ,operational and functional features as the current marketed predicative devices.
The device has been shown to be safe and effective when it is used as labelled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

Kai Laner
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Finland

Re: K974877
Cranex Tome Ceph, or Cranex Tome
Dated: December 19, 1998
Received: December 29, 1998
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Mr. Laner:

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 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,

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

510 (k) NUMBER : K974877

DEVICE NAME : CRANEX TOME CEPH, or CRANEX TOME

INDICATIONS FOR USE :

Tomographic X-ray System, which is intended for diagnostic dental radiography at the dento-maxillofacial region and additionally cephalometry. The imaging methods are narrow beam radiography and spiral tomography and central projection cephalometry.
The method of image reception is film / intensifying screens.

(PLEASE DO NOT WRITE BELOW THIS LINE-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 K974877