MAR 17 2011

510(k) Summary

K 110371

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: November 15, 2010

1. Company and Correspondent making the submission:
   Name – Panoramic Corp.
   Address – 4321 Goshen rd. , Fort Wayne, IN 46818
   Telephone – 800-654-2027
   Contact – Doug Pack

2. Device :

Trade/proprietary name	: ENCOMPASS HF100- Eagle Panoramic/Cephalometric X-Ray
Common Name	: Dental X-ray
Classification Name	: Extraoral source x-ray system

3. Predicate Device:
   K043307, Cranex D made by Soredex.

4. Classifications Names & Citations :
   21 CFR § 872.1800, Class 2 Product code EHD

5. Description : The ENCOMPASS HF100- Eagle Panoramic X-Ray Machine is a complete system for dental imaging capable of: Film Panoramic Profiles Film Cephalometric Profiles Digital Panoramic Profiles Digital Cephalometric Profiles The digital machines use a sensor with CdTe/CMOS technology for imaging that allows for direct conversion between x-ray photons into voltage levels making it less noisy than traditional scintillator technologies. The equipment has three movement axes (two in orthogonal directions and one rotational) making it possible to execute elaborate imaging profiles. It features a complex profile movement around the dental arch and radiographic emission compensation in the spinal region, when necessary reconstructing the dental arch into a plane image. Each individual profile prioritizes a set of characteristics improving diagnostic capabilities. For example, the standard panoramic prioritizes image layer width, constant vertical magnification and homogeneous exposure along the whole image. Likewise, the low dosage profile prioritizes the reduction of dosage (time and anodic current).

6. Indication for use: For Panoramic or Cephalometric diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

7. Comparison with predicate devices: The Cranex D made by Soredex is a Pan/Ceph device digital image capture system. The new device ENCOMPASS HF100 Eagle is a digital capture type Pan/Ceph system. Technologies employed by the predicates and our new device are nearly identical.

8. Safety, EMC, Biocompatibility (N/A) and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001). Compliance testing was performed for the applicable portions of the following X-Ray standards: IEC 60601-1-3/2001; IEC 60601-2-7/2001; 60601-2-28/2001; IEC 60601-2-32/2001. Performance testing: Accuracy testing and software validation was performed. All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Panoramic Corp. concludes that the ENCOMPASS HF100- Eagle Panoramic/Cephalometric X-Ray is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Panoramic Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAR 17 2011

Re: K110371
Trade/Device Name: ENCOMPASS HF100-Eagle Panoramic/Cephalometric X-Ray
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 7, 2011
Received: February 8, 2011

Dear Mr. Job:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K110371

Device Name: ENCOMPASS HF100- Eagle Panoramic/Cephalometric X-Ray

Indications for Use:

For Panoramic or Cephalometric diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

Prescription Use_X_____ AND/OR Over-The-Counter Use_____.
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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