JUL 3 0 2014

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**510(k) Summary Page 1 of 2.**
**ENCOMPASS HF100-Eagle Panoramic/Cephalometric X-Ray with CCD sensor**
**K141130**

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

Date prepared: July 28, 2014

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 with CCD sensor
Common Name: Dental Panoramic/Cephalometric X-ray
Classification Name: Extraoral source x-ray system

3. Predicate Device: K110371, Encompass made for Panoramic Corp.

4. Classifications Names & Citations: 21 CFR § 872.1800, Class 2 Product codes MUH (Primary) and EHD (Secondary)

5. Description : The ENCOMPASS HF100-Eagle Panoramic X-Ray Machine with CCD sensor is a complete system for dental imaging capable of Digital Panoramic Profiles and Digital Cephalometric Profiles. The machines use a sensor CCD sensor technology with the traditional scintillator technologies and auto image processing that allow a speed up the diagnostic and improve the clinic workflow. 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). ONLY THE SENSOR HAS CHANGED.

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

7. Comparison with predicate devices: The ENCOMPASS HF100 Eagle with CdTe sensor made for Panoramic is a Pan/Ceph device digital image capture system. The new device ENCOMPASS HF100 Eagle with CCD sensor is a digital capture type Pan/Ceph system. Technologies employed by the predicates and our new device are nearly identical. The resolution figures are as good as or better than our former sensors used in our predicate K110371 .

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**ENCOMPASS HF100-Eagle Panoramic/Cephalometric X-Ray with CCD sensor**
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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. Clinical Summary: We had a licensed dentist review the predicate and new device pan and ceph images. He found them to have comparable diagnostic quality, sharpness, and overall quality.

10. Conclusion: 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 with CCD sensor 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 Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

Panoramic Corporation
% Daniel Kamm, P.E.
Principal Consultant
Kamm and Associates
8870 Ravello Court
NAPLES FL 34114

Re: K141130
Trade/Device Name: Encompass
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source X-Ray system
Regulatory Class: II
Product Code: MUH, EHD
Dated: April 22, 2014
Received: May 1, 2014

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

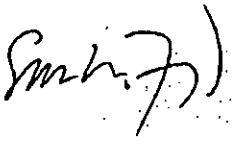
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*

K141130

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

Indications for Use *(Describe)*
For diagnostic radiographic use in dental, oral surgery, and orthodontic practices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

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