510(k) Summary

Date: November 8, 2012

Submitter: Midmark Corporation
675 Heathrow Drive
Lincolnshire, IL 60069 USA

Contact Person: Mark Greenwood
Director, Engineering and Product Development
(847) 415-9800

Device Name: Vantage Panoramic X-Ray System

Classification Name: System, x-ray, extraoral source, digital
(21 CFR 872.1800, Product Code MUH)

Predicate Devices: Instrumentarium Orthopantomograph OP200D (K043612)
Planmeca ProMax (K011619)

Description of Device: The Progeny Vantage Panoramic X-Ray System is an extraoral radiographic imaging system for producing digital radiographs in panoramic and cephalometric views of the teeth, jaw and oral structure.

The Progeny Vantage Panoramic Extraoral Radiographic Imaging System consists of the following main components:

- X-ray tubehead with integrated collimation
- Digital Image Receptor
- Rotating C-Arm for tubehead and image receptor mounting
- Overhead Arm
- Elevating Column
- Patient Positioning Table
- Electronic Control Unit
- Computer Display Workstation
- 8 ft. coil cord with exposure switch
- Optional cephalometric extension arm

Intended Use: The intended use of the Progeny Vantage Extra Oral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric
radiographic examinations for use in orthodontic treatment planning and evaluation.

Substantial Equivalence Comparison:

<table>
<thead>
<tr>
<th>Technical Characteristic</th>
<th>Progeny Vantage</th>
<th>Instrumentarium OP200D</th>
<th>Planmeca ProMax</th>
</tr>
</thead>
<tbody>
<tr>
<td>kVp</td>
<td>60-84 kVp</td>
<td>57-85 kVp</td>
<td>50-84 kVp</td>
</tr>
<tr>
<td>mA</td>
<td>4-14 mA</td>
<td>2-16 mA</td>
<td>.5-16 mA</td>
</tr>
<tr>
<td>Sensor type</td>
<td>CCD</td>
<td>CCD</td>
<td>CCD</td>
</tr>
<tr>
<td>Image Pixel size</td>
<td>96 um</td>
<td>96 um</td>
<td>66, 99, or 132 um</td>
</tr>
<tr>
<td>Panoramic Scan Time</td>
<td>2.5-16s</td>
<td>2.7-14s</td>
<td>2.7-16s</td>
</tr>
<tr>
<td>X-Ray tube focal spot</td>
<td>0.5mm</td>
<td>0.5mm</td>
<td>0.5mm</td>
</tr>
<tr>
<td>Ceph option</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Intended Use for Each Device:

**Progeny Vantage:**
The intended use of the Progeny Vantage Extra Oral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation.

**Instrumentarium OP200D:**
Orthopantomograph OP200 (film unit) and OP200D (digital unit) devices are intended to be used for producing x-ray radiographs of dentition, TM-joints, and other oral structures. The units are capable of taking panoramic, TM-joint, maxillary sinus radiographs from patients. When the units are equipped with cephalometric option Orthoceph OC200 (film unit) and OC200D (digital unit) units can be used for cephalometric radiography and examinations related thereto. OP200 or OC200 units can also be equipped with Ortho Trans (OT) option, which is capable of taking both cross and longitudinal slices of region of interest. Ortho Trans uses linear tomography imaging principle.

**Planmeca ProMax:**
The ProMax, Panoramic X-Ray Imaging System with Cephalostat, is an extraoral source X-Ray System, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. The device can be equipped with accessories to fulfill different diagnostic needs. In digital configuration the images are
displayed on a monitor, and image manipulation, archiving, and communication are performed via a computer.

Technical Analysis: A review of the technical characteristics indicates no significant differences between the Vantage unit and the predicate devices. The radiographic technique factors which would determine patient radiation dosage are almost identical. In fact, many of the key components (x-ray tubes, detectors, etc) are sourced from the same suppliers.

The intended uses of the Vantage unit and the predicate devices also have no significant differences. All three devices’ intended use focuses on providing radiograph examination of the teeth, jaw, and oral structures. The Progeny Vantage and Instrumentarium IFU statements specifically describe cephalometric while the Planmeca refers to more general “different diagnostic needs.” The Instrumentarium unit IFU describes a linear tomography feature which is NOT present in Vantage unit or IFU and therefore should not be considered.

Non-Clinical Tests: The Progeny Vantage Panoramic unit was tested per IEC 61223-3-4 which is an FDA recognized standard for acceptance testing of dental x-ray equipment, specifically Section 7 which is for Cephalometric equipment. The Progeny Vantage with ceph option passed this testing which is a confirmation that the product is safe and effective.

Clinical Tests: Two licensed dentists reviewed images taken of a skull phantom with the Progeny Vantage with Ceph. Both dentists deemed that the image quality was acceptable and that they would be effective as effective as cephalometric images. In addition, the two dentists reviewed images taken of the skull by the Instrumentarium OP200D of the skull phantom and Planmeca sample cephalometric images and concluded that the Progeny Vantage images were at least as effective as the Instrumentarium and Planmeca images.

Conclusion: The Vantage Panoramic X-Ray system is substantially equivalent to other legally marketed devices in the United States. Specifically, the Vantage Panoramic X-Ray system is substantially equivalent in technical characteristics, intended use, and effectiveness to the OP200D marketed by Instrumentarium and the ProMax marketed by Planmeca.
Dear Mr. Greenwood:

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 I (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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure
Indications for Use

510(k) Number (if known): K122643

Device Name: Progeny Vantage Panoramic X-Ray System

Indications For Use:

The indications for use of the Progeny Vantage Panoramic X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation.

Prescription Use X AND/OR Over-The-Counter Use 
(Part 21 CFR 801 Subpart D) (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 Diagnostics and Radiological Health (OIR)

[Signature]

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K122643

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