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**510(k) Summary Statement for the  
Gendex Orthoralix E/GX-9000™ Panoramic Dental System**

**I. General Information**

Submitter: Gendex Dental X-Ray Division Dentsply International, Inc.  
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**II. Names**

Device Name: Orthoralix E/GX-9000™ Panoramic Dental System

Primary Classification Name: Extraoral Source X-Ray System (76 EHD)

**III. Predicate Devices**

- Model PC-1000 marketed by Panoramic Corporation of America
- Versa View marketed by J. Morita, USA Inc.
- Cranex 2.5 + marketed by Sorodex/Orion Corp.
- GX-Pan marketed by Gendex Dental X-Ray Div./Dentsply Int'l, Inc.
- Orthoralix SD2/S marketed by Gendex Dental X-Ray Div./Dentsply Int'l, Inc.

#### **IV. Product Description**

The Dentsply/Gendex Orthoralix E/GX-9000™ is a high frequency panoramic x-ray system for radiographic diagnostic extraoral dental images. It is available in two models: standard pan and pan/ceph.

The Dentsply/Gendex Orthoralix E/GX-9000™ Panoramic X-Ray System is comprised of the following main components:

- High frequency inverter which supplies a true DC output and accurate technique factors
- A microprocessor controlled user-friendly electronic control unit which is configurable in six different languages
- A column to be fixed to the wall
- Counter balanced overhead carriage with controls for patient positioning, setting of technique factors and radiographic projection geometry
- Cassette drive system with flat cassette for 15 x 30 cm film
- X-ray tubehead, with DC power supply via electronic converter
- Remote control box and handswitch
- Optional cephalometric arm and head positioner

During a panoramic exposure, the x-ray tube and cassette holder move around the patient's head. The beam from the x-ray tube is collimated by a slit diaphragm. The flat film cassette passes behind a secondary collimator which blocks the radiation scattered from the patient.

Patient positioning is by means of a bite guide and a headrest. During exposure, the patient remains still while the motorized components rotate.

All movements for the panoramic radiographic projection are performed by two independent motors which are microprocessor controlled.

#### **V.A. Indications For Use/Rationale for Substantial Equivalence**

The Orthoralix E/GX-9000™ Panoramic Dental X-Ray System is used as an extraoral source of x-rays in dental radiography.

It shares the same indications for use, similar materials, design, operational, and functional features and therefore is substantially equivalent to the predicate devices listed in section III of this summary.

## V. Safety and Effectiveness Information

Safety and Effectiveness is demonstrated by:

- performance testing to meet product specifications
- software testing to validate software design/performance
- effective clinical image exposures
- hazard analysis including risk level and solutions
- same indications for use as predicate devices

All the above steps and evaluations combine to demonstrate that the Orthoralix E/GX-9000™ is safe and effective when the device is used as labeled.

## VI. Conclusion

The Orthoralix E/GX-9000™ Panoramic Dental X-Ray System was found to be substantially equivalent to the current marketed predicate devices: PC-1000; Versa View; Cranex 2.5 +; GX-Pan; and the Orthoralix SD2/S.

The Orthoralix E/GX-9000™ share the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices.

It has been shown to be safe and effective when the device is used as labeled.