K965072

JAN 24 1997

EXHIBIT A

Kaycor International Ltd.
3611 Commercial Avenue
Northbrook, IL 60062 USA
847-564-4334
Fax: 847-564-9040
Contact Name: Keith R. Kretchmer
December 18, 1996

510(k) Summary of Safety and Effectiveness

1. Identification of the Device

Classification Name: Extraoral source X-ray system, 76EHD, Reg. # 872.1800

Common/Usual Name: Panoramic dental X-ray system

Proprietary-Trade Name: Panoura ULTRA Pan and Panoura ULTRA Pan/Ceph Panoramic/Cephalometric X-ray Unit.

2. Equivalent legally marketed devices

This product is similar in design and function to the Yoshida/Kaycor Panoura-10 Panoramic X-ray Unit, and Yoshida Kaycor Panoura-10C Panoramic/Cephalometric X-ray Unit. (K811210)

3. Indications for Use (intended use)

The Panoura ULTRA Pan and Panoura ULTRA Pan/Ceph will be marketed for diagnostic radiographic use in dental, oral surgery, and orthodontic practices, and in other medical facilities where these types of dental radiographs are routinely taken. These uses are typical of the predicate devices in the Panoura-10 series.

4. Description of the Device:

The Panoura ULTRA Pan and Panoura ULTRA Pan/Ceph Panoramic/Cephalometric X-ray Units are microprocessor controlled X-ray generator and film handling units designed mainly for dental applications. The patient stands facing the unit and is positioned by devices built into the unit. The exposure is begun under control of the operator, and the X-ray source and film rotate so as to produce a panoramic film for diagnostic use.

5. Safety and Effectiveness, comparison to predicate device.

The Panoura ULTRA Pan and Panoura ULTRA Pan/Ceph Panoramic/Cephalometric X-ray Units, are substantially equivalent to the Yoshida/Kaycor Panoura-10 Panoramic X-ray Unit, and Yoshida Kaycor Panoura-10C Panoramic/Cephalometric X-ray Units, and are substantially equivalent in safety and effectiveness. Preproduction testing showed that radiographs of the same patient produced on either device were essentially identical. The chart below compares the new and predicate devices.

6. Substantial Equivalence Chart

Feature	Panoura ULTRA Pan and Panoura ULTRA Pan/Ceph (new device)	Panoura-10 Series (predicate device)
X-ray output		
Panoramic mode	6 mA @ 70 - 90 kVp in 6 steps	6 mA @ 70 - 90 kVp continuously variable
Cephalometric mode	10 mA @ 70 - 90 kVp in 6 steps	10 mA @ 70 - 90 kVp continuously variable
Timer		
Panoramic mode	12, 14, or 16 seconds	12 seconds
Cephalometric mode	0.05-4.0 sec., 28 steps	0.4-5.0 sec., 12 steps
X-ray generator	Self-rectified, 50/60 Hz	Self-rectified, 50/60 Hz
X-ray tube	Superior SXR-15 or equal	Toshiba D-103S or equal
Focal spot size	1.0 mm	1.0 mm
Total filtration	2.8 mm Al equiv.	2.8 mm Al. equiv.
Footprint, panoramic	34.06" (86.5 cm) W, 40.0" (101.4 cm) D	34.5" (87.63 cm) W, 41.0" (104.14 cm) D
Footprint, cephalometric	72.0" (182.88 cm) W, 40.0" (101.4 cm) D	72.0" (182.88) W, 41.0 (104.14 cm) D
Control display	Digital	Analog
Maximum tube voltage	90 kVp	90 kVp
Maximum tube current		
Panoramic	6 mA	6 mA
Cephalometric	10 mA	10 mA

7. Conclusion

Since there are no new indications for use nor are there any new potential hazards and preproduction testing showed that radiographs of the same patient produced on either device were essentially identical, Kaycor is of the opinion that the devices are substantially equivalent