

K955643

Attachment 14
510(k) Summary Statement for the
ALARA Imaging System

I. General Information

Submitter: DenOptix Inc.
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II. Names

Device Names: ALARA Imaging System

Primary Classification Name: Electrostatic X-ray Imaging System (90 IXK)

III. Predicate Devices

- Digora device (K934949), marketed by Orion/Soredex;
- DIGISCAN 2 and DIGISCAN (K924459 and K884621), marketed by Siemens Medical Systems, Inc.;
- Computed Radiography DMS CRT Image Consoles (K924012 and K923990), marketed by Fuji Medical Systems USA, Inc.

IV. Product Description

The ALARA Imaging System is digital dental radiography system for using X-ray recording media (phosphor storage screens) for radiographic diagnostic intraoral and extraoral dental images.

ALARA Imaging System is comprised of the following main components:

- Reusable phosphor storage screens (Denta-screens) with commercially available disposable storage screen covers;
- The ALARA Scanner, an image reader/digitizer (laser scanner and optical reader);
- The ALARA Scanner/Workstation Communications Interface;
- The ALARA Imaging System Workstation, with a CRT monitor, a workstation computer (the image processor), a keyboard and mouse (operator interface), proprietary workstation software, a floppy drive, and an optical hard drive (or digital analog tape) that is either resident in or attached to the workstation computer (image storage devices);
- A compatible commercially available laser printer (hard copy device);
- A commercially available light box used to "erase" the phosphor storage screen "eraser"; and
- Any compatible commercially available mass storage device(s) as backup electronic archive device(s).

V. Indications for Use

The ALARA Imaging System is indicated for use digital dental radiography system for using X-ray recording media (phosphor storage screens) for radiographic diagnostic intraoral and extraoral exposures providing interactive CRT retrieval, viewing and processing of stored computed radiographic images.

VI. Rationale for Substantial Equivalence

The ALARA Imaging System shares the same indications for use, similar materials and design features, functional features, and therefore are substantially equivalent to the Digora device (K934949), marketed by Orion/Soredex, the DIGISCAN 2 and DIGISCAN devices (K924459 and K884621), marketed by Siemens Medical Systems, Inc., and the Computed Radiography DMS CRT Image Consoles (K924012 and K923990), marketed by Fuji Medical Systems USA, Inc.

VI. Safety and Effectiveness Information

Physical testing was performed to demonstrate that the performance of the DenOptix phosphor storage screens with the ALARA Imaging System is in accordance with the product specifications and equivalent to the labeled performance of the Digora device. In addition, the plastic envelope material that is used to cover the storage phosphor screens is a commercially available biocompatible product that is used to cover dental X-Ray film to provide protection from cross-contamination.

VI. Conclusion

The ALARA Imaging System was found to be substantially equivalent to the currently marketed predicate devices, the Digora, the DIGISCAN 2 and DIGISCAN, and the Computed Radiography DMS CRT Image Consoles. The ALARA Imaging Systems share the same indications for use, similar design features, and similar functional features as the currently marketed Digora, DIGISCAN 2 and DIGISCAN, and Computed Radiography DMS CRT Image Consoles. The physical test results demonstrated that the Alara imaging system have acceptable performance characteristics.

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