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-- 510(k) SUMMARY --

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K955237

9. Safety and Effectiveness Information

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9.2 Device Name: *TigerScan / TigerView*

9.3 Equivalent Device: Dental Link, FDA registration number K930527/A

9.4 Device Description

TigerScan and *TigerView* are software packages designed to run on industry standard PC-compatible computers. This software is designed to support; dental radiograph scanning to convert film to digital form, storage and retrieval of radiographs by patient, electronic transmission to specialists and insurance companies, and diagnostic review of radiograph images. With *TigerScan* and *TigerView*, scanning is accomplished with a commercially available flatbed scanner interfaced to the PC. The difference between the two products is:

TigerScan is designed exclusively for the electronic submission of radiographs in support of dental insurance claims. Designed to be used by the office administrator, the software is simple and easy to use in an standardized scan, quick review, transmit sequence. *TigerScan's* intelligent scanning module insures that diagnostic image quality is maintained and requires little or no operator intervention. When using *TigerScan*, radiographs are deleted immediately after they are successfully sent to their destination, images are not retained in a database for later review.

TigerView is a fully functional digital radiograph scanning, archive, electronic transmission, and diagnostic review system. Features include; advanced graphical user interface, intelligent scanning, scanning and display of full-mouth sets and other mounts, high-resolution image display and manipulation, electronic transmission and receipt of digital radiographs, large on-line database of radiographs organized by patient, and interfaces to practice management systems. In addition to

9.5 Intended Use

Uses for *TigerScan* and *TigerView* in the dental industry include the following:

- Scanning of film and archival storage for on-line access by patient.
- Electronic transmission of digital radiographs with insurance claims.
- Radiograph viewing and manipulation for Insurance claims adjudication
- Radiograph viewing and manipulation for diagnostic purposes.
- Radiograph viewing for patient education and consultation.
- Electronic transmission of radiographs to specialists for consultation.

When used for diagnostic purposes, the patient population will be the general public, and the diseases / conditions that the device will be used to diagnose are; dental caries, periodontal disease and bone loss, tooth fractures, jaw misalignment, and other diseases and conditions that are encountered by general practitioners and specialists in the dental care field.

9.6 Technological Characteristics

TigerScan and *TigerView* have the same technological characteristics as the predicate device, Dental Link. A summary of the technologies employed in these devices follows:

<u>Technology</u>	<u>Use in Device</u>
Image Scanner	Conversion of film to digital image.
Personal Computer	Control of scanner; storage, retrieval, transmission, and receipt of digital images.
Graphical User Interface	Mouse, windows, menus, etc. used to control device.
Modem	Transmission of digital images over phone lines.
Image Processing	Image display and manipulation.

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