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510(k) SUMMARY

[As required by 21 CFR 807.92(a)]

A. Submitter Information

Submitter's Name: Aurora Technology

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B. Device Information

Trade Name: Aurora™ Diagnostic Workstation.

Common Name: Medical Imaging Workstation, a component of picture archiving and communications systems (PACS).

Classification Name: No formal classifications have been issued for PACS or PACS components. For purposes of determining substantial equivalence, they have been considered to be accessories to medical imaging devices.

Predicate Device: Aurora Technology believes that the Aurora workstation components are substantially equivalent to other commercially available medical image displays, specifically, the user retrieval and image viewing stations manufactured by Eltrax Systems, Inc. (now Emerald Archiving, Inc.).

Device Description: The Aurora Medical Imaging Workstation consists of a personal computer, a "Processor " board set for decompression of tiled, stored images; up to eight high resolution (1024 x 1280) monochrome CRT monitors; up to eight video controller boards to display and store the image; a retrieval monitor; and proprietary software for retrieval, image handling and the user interface.

Intended Use: The intended use of the Aurora Diagnostic Workstation is identical to other commercially available medical imaging workstations.

C. Comparison of Required Technological Characteristics

Aurora Technology considers the Aurora diagnostic imaging workstation to be substantially equivalent in device design, function, and intended use to user retrieval and image viewing stations manufactured by Eltrax Systems, Inc. (now called Emerald Archiving, Inc.) and other commercially available medical image displays.

Characteristics	Aurora Medical Imaging Workstation
a. Product Labeling	Substantially equivalent
b. Intended Use	Identical
c. Physical Characteristics	Substantially equivalent
d. Anatomical Sites	N/A
e. Target Population	Identical
f. Performance Testing	Substantially equivalent
g. Safety Characteristics	Substantially equivalent

D. Summary of Nonclinical Tests

The devices used in the Aurora workstations are not new or significantly improved devices. Except for proprietary processor and video controller board and related software, all components are commercially available.