

K965203

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510(K) SUMMARY FOR
ELECTRO MEDICAL SYSTEMS
RAD_x SYSTEM

1. DATE THIS SUMMARY WAS PREPARED

December 24, 1996

2. SUBMITTER'S NAME AND ADDRESS

Electro Medical Systems
670 International Parkway, Suite 100
Richardson, TX 75081

3. CONTACT PERSON

Ms. Kathryn Hamilton
Electro Medical Systems
Telephone (972)690-8382
Facsimile (972)690-8981

4. DEVICE NAME

Trade/Proprietary Name: RAD_x System
Common Name: Longitudinal Radiographic Analysis System
Classification Name: Accessory to Stationary X-ray Systems

5. PREDICATE DEVICES

The legally marketed device to which equivalence is being claimed is the DXS Digital Subtraction Radiography Image Processor manufactured by Picker International which was cleared under premarket notification K914376.

6. DEVICE DESCRIPTION

The RAD_x System enables the dental practitioner to take a longitudinal series of X-rays using the long-cone paralleling technique, digitize the resulting images, and perform digital subtraction analysis to detect very small changes in bone densities.

The RAD_x System consists of a high resolution digital image scanner and the RAD_x software program.

Also required are an IBM compatible personal computer, a long cone, and a parallel aiming system.

The ability of the RAD_x System to create spatially registered images for comparison without the use of rigid projection geometry allows longitudinal radiographic analysis using equipment readily available to the average dental practitioner.

7. INTENDED USE

The RAD_x System digitizes and processes dental radiographs to perform longitudinal radiographic analysis using the digital subtraction technique. This technique is helpful in the detection of hard tissue changes including pathologies as well as resolution of those same pathologies.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The EMS RAD_x System and the Picker International DXS System are both intended for digitizing, storing, and performing digital image subtraction analysis on radiographic images. Both systems aid the practitioner in recognizing certain features and making certain diagnoses using the well-accepted technique of digital image subtraction.

9. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the RAD_x software has been thoroughly validated and documented. Non-clinical tests were conducted to evaluate the suitability of commercially available scanners for digitizing x-rays and to verify that the warping algorithm reduces registration error to a level that is well within the range reported in the literature for accepted manual registration methods and either alignment stent or long source-to-object projection techniques.

10. CONCLUSIONS FROM NONCLINICAL TESTING

The testing of the RAD_x System demonstrates that the performance is substantially equivalent to predicate devices cited above.