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SECTRA

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Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification Section

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510(k) summary of safety and effectiveness information for the SECTRA Teleradiology System TRS 2000

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The TRS 2000 system is a teleradiology system/transmission and advance reviewing station X-ray images. TRS 2000 is used for advanced reviewing and transmission over private or public telecommunications networks of radiological images. Typical users are phycians and nurses at a radiology deparment.

The undersigned certifies that the 510(k) Pre-Market Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence to Philips PMS EasyVision (K920950). This information and data is summarized as follows:

1. The Teleradiology system TRS is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.

2. The TRS system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed External Standards survey.

3. The TRS User's Guide contains comprehensive and extensive information on how to operate the system to ensure a safe and effective use.

4. Close co-operation with radiologists from the specifications to test phases and substantial independent experience from clinical operation has shown the TRS system to be safe and effective. Past experience with substantially equivalent predicate devices has also shown our device to be safe and effective when used as directed in the User's Guide.

5. The submission contains the results of an hazard analysis.

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