

OCT 28 1996

**"SUMMARY OF SAFETY AND EFFECTIVENESS
INFORMATION"**

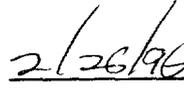
**for the BIO-IMAGING RESEARCH SLS-CT System
510(k) PREMARKET NOTIFICATION**

K960985

"This 510(k) Summary of Safety and Effectiveness Information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990."



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Date

The SLS-CT System manufactured by Bio-Imaging Research (BIR) is a passive add-on option to Philips Medical Systems, Inc.'s existing, legally marketed, Radiotherapy Simulators. The SLS-CT does not control the Simulator x-ray and mechanical functions. The SLS-CT is a data gathering device that allows the Radiographic Simulators to process data into tomographic images. The SLS-CT is not a diagnostic tool.

The SLS-CT System complies with voluntary standards IEC601, UL 2601, and CSA 601. The SLS-CT software was developed utilizing the IEEE Software Engineering Standard as a model.

System and software requirements specifications were developed in concert with Philips Medical Systems. Modular testing of the hardware and software has been performed to the specifications. A hazard analysis of the hardware and software was performed by both Philips Medical Systems and BIR with safeguards instituted. Stringent software and hardware design and quality assurance procedures were adhered to. Stringent system verification and validation testing was performed per documented procedures during two Beta tests, with Beta Test 1 being performed at Philips Medical Systems and Beta Test 2 in a clinical setting. In-house verification and validation was performed by BIR. Operator, System Validation and Maintenance, and Service Manuals, along with Customer Acceptance Test Schedule documents provide the user with clear and concise information thus ensuring the safe and effective operation of the system.

BIR's manufacturing facility strictly adheres to and believes in the FDA's Good Manufacturing Practices. BIR's Quality System is certified to ISO9001 for the design, manufacturing, and service of medical imaging equipment.