

Dec. 6, 1996

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Philips Medical Systems - Radiotherapy, hereby provide the following material summarising safety and effectiveness information for the Philips SLi Series Linear Accelerators and MLCi products. This information is summarised as follows:-

- 1) The SLi Series Linear Accelerators and MLCi products are improvements of the existing SL Series and the Philips MLC products which have previously been cleared for commercial distribution. These devices have an established and proven track record for safety. The SLi Series Linear Accelerators and MLCi products do not raise additional types of safety or effectiveness considerations when compared against the existing functions provided by the Philips SL Series fitted with MLC.
- 2) The accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed by the accompanying documents provided for the user.
- 3) It is our opinion that the Philips SLi Series Linear Accelerators and MLCi products do not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider them an enhancement to the existing SL Series Linear Accelerators and MLC products.
- 4) The SLi Series Linear Accelerators and MLCi products have been subject to compliance testing as defined in the internationally recognised safety standards IEC 601-1 and IEC 601-2-1. As appropriate, proprietary information technology equipment is procured to the internationally recognised standards IEC 950 and/or UL 1950.
- 5) All products bear the CE mark affirming compliance with all relevant European Directives in force. In particular compliance has been assured to the European Medical Device Directive and the European Electromagnetic Compatibility Directive. Additionally the total system is subject to the provision of the Code of Federal Regulations, Title 21: Food and Drugs.
- 6) The SLi Series Linear Accelerators and MLCi products have been designed to ensure that compliance to the above standards is maintained.

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- 7) PMS-R is a Department of Health GMP registered medical device manufacturer of assessed capability, against the requirements of ISO 9001, EN 46001, and the UK Department of Health GMP. This Software Quality System has been established to satisfy the requirements of ISO 9001, EN 46001, the UK Department of Health GMP and the US 21 CFR 820 GMP. Philips Medical Systems - Radiotherapy has developed the SLi Series Linear Accelerators and the MLCi products using an established and documented Software Quality Management System.
- 8) In accordance with the above requirements all parts of the Quality System are subject to periodic and systematic internal Quality Audits. These audits are performed by trained personnel not having direct responsibilities in the functions being audited.
- 9) Additionally the quality system is subject to regular, planned and documented GMP audits conducted by external auditors from the UK Department of Health, SGS Yarsley and the FDA.
- 10) PMS-R has conducted hazard analysis on the Philips SLi Series Linear Accelerators and the MLCi products and have concluded that it introduces no new hazards and that the level of concern appropriate to the SLi Series Linear Accelerators and the MLCi products is moderate.

Signature 
Development Director

Signature 
Company Marketing Manager

Signature 
Quality Assurance Manager

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