

ENS

K96190

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Information: Dated: May 13, 1996
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Common or Usual Name: Radiation therapy beam shaping block
Proprietary Name: **Siemens Multileaf Collimator Beam Shaper**
Classification Names: Radiation therapy beam shaping block - 21 CFR § 892.5710
Class II, Product Code: RA 90 IXI

Predicate Device: Siemens Multileaf Collimator Hand Control
K953894

AUG - 8 1996

Description of Device: Beam Shaper consists of a digitizer tablet for inputting leaf positions based on field shapes traced from an x-ray film or paper diagram to generate Multileaf Collimator leaf plans. In specifying field geometry, Beam Shaper utilizes leaf, jaw collimator, and gantry position information.

Statement of intended use: The MLC Beam Shaper software utility provides the ability to create, view, and edit geometric information that will be utilized to form irregular treatment fields through automated changes of multiple leaves that conform to the specified treatment target generate treatment field shapes. The MLC Beam Shaper software is an accessory to the Siemens Multileaf Collimator with Lantis Record and Verify System for the Siemens Digital MEVATRON radiation treatment system.

The intended use is the same the predicate device.

Statement of technological characteristics: The Siemens Multileaf Collimator Beam Shaper software does not have significant change in materials, energy source or performance characteristics compared to the predicate devices.

The intended use and the performance characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to it.

Differences: The minor configuration and specification differences between the Siemens Multileaf Collimator Beam Shaper software and that of the MLC hand control does not alter the intended use or affect the safety and effectiveness of the Siemens Multileaf Collimator Beam Shaper when used as labeled.

Performance Evaluation: Performance tests were conducted and the results indicated that the device consistently performed within the design parameters and equivalently to the predicate device.

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