



K910303

GE Medical Systems

General Electric Company
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SUMMARY OF SAFETY AND EFFECTIVENESS
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This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

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Identification of Product The Multileaf Collimator Option is a versatile therapy beam collimation system designed for use on GE Saturne medical charged-particle radiation therapy systems. It is manufactured by GE Medical Systems Europe, 283 Rue de la Miniere, 78530 Buc, France and is distributed by GE Medical Systems, Milwaukee, WI.

Marketed Devices The current family of Saturne therapy systems uses rectangular field collimators in combination with external beam blockers to contour the treatment field to the desired shape. The Multileaf collimator will permit the use of irregular treatment field shapes to better conform the treatment field to the desired shape without external beam blockers for some treatments.

Device Description The Multileaf collimator consists of the collimator assembly, a collimator accessory tray and electron applicators, collimator control and display functions on the Saturne operator console, and a Treatment Preparation Console and film digitizer. The accelerator radiation head and Multileaf collimator are assembled in a rotating gantry fastened to a wall. The existing treatment couch is used to support and position the patient.

Indications for Use The Saturne Multileaf collimator is intended to be used for radiation therapy.

Comparison with Predicate Saturne Multileaf collimators perform the same function as Multileaf collimators produced by Varian Associates and Philips Medical Systems. Other device characteristics are either the same or comparable for the various collimator systems.

Conclusion It is the opinion of GE Medical Systems that Saturne Multileaf collimators are substantially equivalent to the named predicate devices based on the similarities in operation and intended use. The Saturne Multileaf collimators are as safe and perform as well as the predicate devices and raise no new questions of safety or effectiveness.



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