

PREMARKET NOTIFICATION [510(k)] SUMMARY

**Trade Name:** RPS-50 Beam Scanner

**Common Name:** Beam scanner for clinical linear accelerator

**Classification Name and Number:** None given

**Class:** Class II, accessory to a linear accelerator

**Predicate:** A.R.M. beam scanner; control number K933558

**Description:** The RPS-50 scanner consists of a water tank, linear scanning guides, electronic control of movement, chamber bias, and system gain control. A software program controls all movements and necessary electronic signals. The scanner moves a radiation detector through a field of high radiation and presents the collected data as a plot on a computer screen, as a table of data or on a floppy disk suitable for use in a treatment planning system.

**Intended Use:** The RPS-50 is intended to be used as an accessory to a linear accelerator under the direct control of a qualified individual (usually a therapeutic radiation physicist.) The scanner may be used for acceptance testing of new accelerators, quality control of existing accelerators, or for the collection of data necessary for the operation of a computerized treatment planning system.

**Technological Characteristics:** The technological characteristics of the RPS-50 scanner and the predicate device are the same in that both are meant to collect beam data descriptive of the accelerator scanned. The data for both devices is evaluated by a clinical physicist for completeness and accuracy.

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