

**K112778 SMART SEGMENTATION-KNOWLEDGE BASED
CONTOURING**Dec 29, 2011
94 days to decisionK112778 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k112778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 26, 2011
Decision date	Dec 29, 2011
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems
Location	Palo Alto, CA, US
Contact	VY TRAN
Website	http://www.varian.com
510(k) history	32 submissions · 32 cleared · 2001-2025

Varian Medical Systems is an American radiation oncology company based in Palo Alto, California. The company develops medical devices and software for cancer treatment and radiotherapy. Varian Medical Systems has received FDA 510(k) clearances from total submissions since 2001. The company specializes exclusively in Radiology devices, with its latest clearance in 2025, demonstrating continued regulatory activity and innovation in this field. The company's Radiology portfolio includes linear accelerators, treatment planning systems, applicator sets, and proton therapy syst...

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Device record: <https://www.510kdatabase.net/k112778/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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