

K123137 CALYPSO SYSTEMDec 5, 2012
61 days to decisionK123137 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k123137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 5, 2012
Decision date	Dec 5, 2012
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems
Location	Palo Alto, CA, US
Contact	MARCIA PAGE
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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