

**K250099 Mobius3D (4.1)**May 16, 2025  
122 days to decisionK250099 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k250099/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 14, 2025
Decision date	May 16, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Varian Medical Systems</b>
Location	Palo Alto, CA, US
Contact	Lynn Allman
Website	<a href="http://www.varian.com">http://www.varian.com</a>
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...