

K261306 AI Contouring (VA10A)

Jul 10, 2026
81 days to decision

K261306 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k261306/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Apr 20, 2026
Decision date	Jul 10, 2026
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems
Location	Palo Alto, CA, US
Contact	Lynn Allman
Website	http://www.varian.com
510(k) history	34 submissions · 34 cleared · 2001-2026

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...