

## K241853 Titanium Fletcher-Style Applicator Set Defined Geometry

Nov 7, 2024  
133 days to decisionK241853 · Product code: **JAQ** · Radiology  
Source: <https://www.510kdatabase.net/k241853/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Jun 27, 2024
Decision date	Nov 7, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Smit Cervical Sleeve

### APPLICANT

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Company	<b>Varian Medical Systems, Inc.</b>
Location	Palo Alto, CA, US
Contact	Lynn Allman
Website	<a href="http://www.varian.com">http://www.varian.com</a>
510(k) history	169 submissions · 169 cleared · 1997-2026

Varian Medical Systems, Inc. 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, Inc. has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's regulatory portfolio is dominated by Radiology devices, representing 96% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. The company specializes in linear accelerators (LINACs), ra...