

K221791 ProBeam 360° Proton Therapy SystemDec 1, 2022
163 days to decisionK221791 · Product code: **LHN** · Radiology
Source: <https://www.510kdatabase.net/k221791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Charged-particle, Medical (LHN)
Date received	Jun 21, 2022
Decision date	Dec 1, 2022
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Varian Medical Systems, Inc.
Location	Palo Alto, CA, US
Contact	Peter J. Coronado
Website	http://www.varian.com
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...

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Device record: <https://www.510kdatabase.net/k221791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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