

K222941 Halcyon, Ethos Radiotherapy SystemJan 17, 2023
113 days to decisionK222941 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k222941/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Sep 26, 2022 |
| Decision date | Jan 17, 2023 |
| Days to decision | 113 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...