

**K241965 Catheter Surface Flap Applicator Set (GM11011830)**Oct 29, 2024  
118 days to decisionK241965 · Product code: **JAQ** · Radiology  
Source: <https://www.510kdatabase.net/k241965/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | System, Applicator, Radionuclide, Remote-controlled (JAQ) |
| Date received         | Jul 3, 2024   |
| Decision date         | Oct 29, 2024  |
| Days to decision      | 118 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...