

**K183037 Monaco RTP System**Dec 4, 2018  
33 days to decisionK183037 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k183037/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | System, Planning, Radiation Therapy Treatment (MUJ) |
| Date received         | Nov 1, 2018   |
| Decision date         | Dec 4, 2018   |
| Days to decision      | 33 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Elekta, Inc.</b>                   |
| Location       | Norcross, GA, US                      |
| Contact        | Kathryn Stinson                       |
| 510(k) history | 4 submissions · 4 cleared · 2005-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183037/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026