

K190178 Monaco RTP SystemMar 29, 2019
56 days to decisionK190178 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k190178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Feb 1, 2019
Decision date	Mar 29, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190178/> Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026