

K202789 Monaco Rtp SystemFeb 23, 2021
154 days to decisionK202789 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k202789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Sep 22, 2020
Decision date	Feb 23, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elekta Solutions AB
Location	Stockholm, SE
Contact	Irina Proutski
510(k) history	14 submissions · 14 cleared · 2020-2026

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