

K213787 Monaco RTP SystemMay 17, 2022
162 days to decisionK213787 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k213787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Dec 6, 2021
Decision date	May 17, 2022
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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