FDA 510(k) Premarket Notification

K223233 Monaco RTP System

CLEARED

Feb 23, 2023
127 days to decision

K223233 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k223233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Oct 19, 2022
Decision date	Feb 23, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Elekta, Inc.**
Contact	Melinda Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov