

K211841 MRI PlannerAug 25, 2022
437 days to decisionK211841 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k211841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jun 14, 2021
Decision date	Aug 25, 2022
Days to decision	437 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spectronic Medical AB
Location	Helsingborg, SE
Contact	Per Bruhn
510(k) history	1 submissions · 1 cleared · 2022-2022

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