

K190387 RayStationJun 19, 2019
120 days to decisionK190387 · Product code: **MUJ** · Radiology
Source: <https://www.510kdatabase.net/k190387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Feb 19, 2019
Decision date	Jun 19, 2019
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	RaySearch Laboratories AB (PUBL)
Location	Stockholm, SE
Contact	David Hedfors
510(k) history	15 submissions · 15 cleared · 2016-2025

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