

K200600 SentinelApr 20, 2020
42 days to decisionK200600 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k200600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 9, 2020
Decision date	Apr 20, 2020
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	C-Rad Positioning AB
Location	Uppsala, SE
Contact	Thomas Matzen
510(k) history	6 submissions · 6 cleared · 2007-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200600/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026