

K213053 Gold AnchorJan 6, 2022
106 days to decisionK213053 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k213053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 22, 2021
Decision date	Jan 6, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Naslund Medical AB
Location	Huddinge, SE
Contact	Tomas Näslund
510(k) history	4 submissions · 4 cleared · 2009-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213053/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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