

K213137 INTDoseMay 13, 2022
228 days to decisionK213137 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k213137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 27, 2021
Decision date	May 13, 2022
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carina Medical, LLC
Location	Lexington, KY, US
Contact	Xue Feng
510(k) history	2 submissions · 2 cleared · 2022-2022

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