

**K212274 INT Contour**Apr 8, 2022  
262 days to decisionK212274 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k212274/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jul 20, 2021
Decision date	Apr 8, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212274/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026