

**K210664 DABRA Laser System (DABRA Laser model RA-308 and DABRA Catheter model 101)**Jul 27, 2021  
144 days to decisionK210664 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Mar 5, 2021
Decision date	Jul 27, 2021
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ra Medical Systems, Inc</b>
Location	Carlsbad, CA, US
Contact	Jami Miller
510(k) history	4 submissions · 4 cleared · 2007-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210664/>. 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 26, 2026