

**K203822 ProFound AI Software V3.0**Mar 12, 2021  
73 days to decisionK203822 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k203822/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Dec 29, 2020
Decision date	Mar 12, 2021
Days to decision	73 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icad, Inc.</b>
Location	Beavercreek, OH, US
Contact	Heather Reed
510(k) history	14 submissions · 14 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203822/> 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