

**K222198 Exo Iris (EI2001)**Nov 9, 2022  
110 days to decisionK222198 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k222198/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 22, 2022
Decision date	Nov 9, 2022
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Exo Imaging, Inc.</b>
Location	Redwood City, CA, US
Contact	Antoanela Gomard
510(k) history	2 submissions · 2 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222198/> 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