

**K212851 EchoSK and EchoSGyn modules for EchoS Family devices**Mar 16, 2022  
190 days to decisionK212851 · Product code: IYO · Radiology  
Source: <https://www.510kdatabase.net/k212851/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 7, 2021
Decision date	Mar 16, 2022
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Echolight S.P.A</b>
Location	Lecce, IT
Contact	Giuseppe Criscenti
510(k) history	3 submissions · 3 cleared · 2018-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212851/>. 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