

**K241662 Ultrasound Transducer Cover**Aug 30, 2024  
81 days to decisionK241662 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k241662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jun 10, 2024
Decision date	Aug 30, 2024
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitrolife Sweden AB</b>
Location	Ringoes, NJ, US
Contact	Lin Huldeberg
510(k) history	38 submissions · 38 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241662/> 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 13, 2026