

**K153212 Sheathes Ultrasound Probe Covers**Mar 4, 2016  
120 days to decisionK153212 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k153212/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Nov 5, 2015
Decision date	Mar 4, 2016
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sheathing Technologies, Inc.</b>
Location	Morgan Hill, CA, US
Contact	JENNIFER DOWNING
510(k) history	7 submissions · 7 cleared · 1999-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153212/> 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 16, 2026