

**K180621 EchoMark, EchoMark LP**Jun 6, 2018  
89 days to decisionK180621 · Product code: **NEU** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k180621/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Mar 9, 2018
Decision date	Jun 6, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sonavex, Inc.</b>
Location	Baltimore, MD, US
Contact	David Narrow
510(k) history	3 submissions · 3 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180621/> 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