

**K160573 FirstSense Breast Exam**Jun 1, 2016  
93 days to decisionK160573 · Product code: **LHQ** · Radiology  
Source: <https://www.510kdatabase.net/k160573/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Feb 29, 2016
Decision date	Jun 1, 2016
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>First Sense Medical, LLC</b>
Location	Pontiac, MI, US
Contact	Paul G. Angott
510(k) history	2 submissions · 2 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160573/> 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