

K162767 Sentinel BreastScan II SystemJan 9, 2017
101 days to decisionK162767 · Product code: **LHQ** · Radiology
Source: <https://www.510kdatabase.net/k162767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Telethermographic (adjunctive Use) (LHQ)
Date received	Sep 30, 2016
Decision date	Jan 9, 2017
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	First Sense Medical, LLC
Location	Pontiac, MI, US
Contact	Alan Alan Klevens
510(k) history	2 submissions · 2 cleared · 2016-2017

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