

**K190575 iBreastExam**Jul 16, 2019  
132 days to decisionK190575 · Product code: **NKA** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k190575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Documentation, Breast Lesion (NKA)
Date received	Mar 6, 2019
Decision date	Jul 16, 2019
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ue Lifesciences, Inc.</b>
Location	Chester Springs, PA, US
Contact	Mihir Shah
510(k) history	3 submissions · 3 cleared · 2012-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190575/> 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 June 19, 2026