

K142926 iBreastExamApr 23, 2015
197 days to decisionK142926 · Product code: **NKA** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k142926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Documentation, Breast Lesion (NKA)
Date received	Oct 8, 2014
Decision date	Apr 23, 2015
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ue Lifesciences, Inc.
Location	Chester Springs, PA, US
Contact	MIHIR SHAH
510(k) history	3 submissions · 3 cleared · 2012-2019

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