

K181672 SureTouch Mobile Pressure Mapping SystemJun 28, 2019
368 days to decisionK181672 · Product code: **NKA** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k181672/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Documentation, Breast Lesion (NKA)
Date received	Jun 25, 2018
Decision date	Jun 28, 2019
Days to decision	368 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sure, Inc.
Location	Palos Verdes Estates, CA, US
Contact	David Ables
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Certified Compliance Solutions
Contact	Laurence Harvey

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181672/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026