

K182421 Senhance Ultrasonic SystemJan 11, 2019
128 days to decisionK182421 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k182421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Sep 5, 2018
Decision date	Jan 11, 2019
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Transenterix, Inc.
Location	Durham, NC, US
Contact	Stephanie M. Fitts
510(k) history	15 submissions · 15 cleared · 2009-2021

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