

K200886 StimSiteNov 10, 2020
222 days to decisionK200886 · Product code: **ETN** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k200886/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Apr 2, 2020
Decision date	Nov 10, 2020
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Allotrope Medical, Inc.
Location	Houston, TX, US
Contact	Albert Huang
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200886/> 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 28, 2026