

K201077 Strados Remote Electronic Stethoscope Platform (RESP)Dec 20, 2020
242 days to decisionK201077 · Product code: **DSH** · Anesthesiology
Source: <https://www.510kdatabase.net/k201077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Apr 22, 2020
Decision date	Dec 20, 2020
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Strados Labs
Location	Philadelphia, PA, US
Contact	Nicholas Delmonico
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Powers Regulatory Consulting/64954
Contact	Grace Powers

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/k201077/>; 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