FDA 510(k) Premarket Notification

CLEARED

K201077 Strados Remote Electronic Stethoscope Platform (RESP)

Dec 20, 2020
242 days to decision

K201077 · 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