FDA 510(k) Premarket Notification

K183710 Vivio System

CLEARED

Oct 4, 2019
277 days to decision

K183710 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k183710/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Dec 31, 2018
Decision date	Oct 4, 2019
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avicena, LLC**
Location	Altadena, CA, US
Contact	Sean Brady
510(k) history	2 submissions · 2 cleared · 2019-2023