

K183710 Vivio SystemOct 4, 2019
277 days to decisionK183710 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183710/> 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 May 26, 2026