

K223785 N9+Apr 14, 2023
119 days to decisionK223785 · Product code: **DQD** · Cardiovascular
Source: <https://www.510kdatabase.net/k223785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Dec 16, 2022
Decision date	Apr 14, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nonagon , Ltd.
Location	Caesarea, IL
Contact	Orly Maor
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US Lpp
Contact	Jonathan Kahan

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/k223785/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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