FDA 510(k) Premarket Notification

K223785 N9+

CLEARED

Apr 14, 2023
119 days to decision

K223785 · 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