

K260332 EchoNextJun 8, 2026
126 days to decisionK260332 · Product code: **QXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k260332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiovascular Machine Learning-based Notification Software (QXO)
Date received	Feb 2, 2026
Decision date	Jun 8, 2026
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pathwai, Inc.
Location	New York, NY, US
Contact	Pierre Elias
510(k) history	1 submissions · 1 cleared · 2026-2026

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