

K212219 AHI SystemDec 3, 2021
140 days to decisionK212219 · Product code: **QNV** · Cardiovascular
Source: <https://www.510kdatabase.net/k212219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Hemodynamic Indicator With Decision Point (QNV)
Date received	Jul 16, 2021
Decision date	Dec 3, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fifth Eye, Inc.
Location	Ann Arbor, MI, US
Contact	Jennifer A. Baird
510(k) history	3 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Donna-Bea Tillman

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/k212219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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