FDA 510(k) Premarket Notification

K221203 AHI System

CLEARED

Jul 14, 2022
79 days to decision

K221203 · Product code: **QNV** · Cardiovascular
Source: https://www.510kdatabase.net/k221203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adjunctive Hemodynamic Indicator With Decision Point (QNV)
Date received	Apr 26, 2022
Decision date	Jul 14, 2022
Days to decision	79 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 Baird
510(k) history	3 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting**
Contact	Donna-Bea Tillman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov