FDA 510(k) Premarket Notification

CLEARED

K241766 QMAPP® (Hemo, Hemo Lite, PCM, GO, Hybrid)

Aug 27, 2025
433 days to decision

K241766 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k241766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 20, 2024
Decision date	Aug 27, 2025
Days to decision	433 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fysicon BV**
Location	Oss, NL
Contact	Cornelis (Eric) Van Antwerpen
510(k) history	2 submissions · 2 cleared · 2017-2025

REGULATORY CONSULTANT

Consulting firm	**Trisler Consulting**
Contact	Patsy Trisler

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