FDA 510(k) Premarket Notification

K223818 Model 9160 VitaloQUB

CLEARED

May 25, 2023
155 days to decision

K223818 · Product code: **JEH** · Anesthesiology
Source: https://www.510kdatabase.net/k223818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Volume (JEH)
Date received	Dec 21, 2022
Decision date	May 25, 2023
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vitalograph (Ireland) , Ltd.**
Location	Ennis, Co. Clare, IE
Contact	Tony O'Hanlon
510(k) history	12 submissions · 12 cleared · 2008-2023

REGULATORY CONSULTANT

Consulting firm	**ProMedic, LLC**
Contact	Paul Dryden

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