FDA 510(k) Premarket Notification

K221030 Model 9100 PFT/DICO

CLEARED

Jul 15, 2022
99 days to decision

K221030 · Product code: **BTY** · Anesthesiology
Source: https://www.510kdatabase.net/k221030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Apr 7, 2022
Decision date	Jul 15, 2022
Days to decision	99 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