

**K221030 Model 9100 PFT/DICO**Jul 15, 2022  
99 days to decisionK221030 · Product code: **BTY** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221030/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedic, LLC</b>
Contact	Paul Dryden

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221030/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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