

K181524 Vyntus ONE with CART, Vyntus ONE PFT only with CART, Vyntus ONE with adjustable CART, Vyntus ONE PFT only with adjustable CARTNov 30, 2018
172 days to decisionK181524 · Product code: **BZC** · Anesthesiology
Source: <https://www.510kdatabase.net/k181524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Pulmonary Function Data (BZC)
Date received	Jun 11, 2018
Decision date	Nov 30, 2018
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vyaire Medical, Inc.
Location	Helsinki, FI
Contact	Elmar Niedermeyer
510(k) history	9 submissions · 9 cleared · 2018-2024

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