FDA 510(k) Premarket Notification

K190853 Vyntus BODY

CLEARED

Aug 16, 2019
136 days to decision

K190853 · Product code: **BZC** · Anesthesiology
Source: https://www.510kdatabase.net/k190853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Pulmonary Function Data (BZC)
Date received	Apr 2, 2019
Decision date	Aug 16, 2019
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k190853/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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