

K233666 CorVista System with PH Add-OnApr 5, 2024
142 days to decisionK233666 · Product code: **SAT** · Cardiovascular
Source: <https://www.510kdatabase.net/k233666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulmonary Hypertension Machine Learning-based Notification Software (SAT)
Date received	Nov 15, 2023
Decision date	Apr 5, 2024
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Analytics For Life, Inc.
Location	Toronto, CA
Contact	Gabrielle Zaeska
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233666/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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