

K192604 Servo-air 4.0 Ventilator SystemJun 18, 2020
272 days to decisionK192604 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k192604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Sep 20, 2019
Decision date	Jun 18, 2020
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Critica Care AB
Location	Solna, SE
Contact	David Ardanius
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Getinge
Contact	Mark N. Smith

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

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