

**K201874 Servo-u Ventilator System 4.1, Servo-n Ventilator System 4.1, Servo-u MR Ventilator System 4.1**Apr 20, 2021  
287 days to decisionK201874 · Product code: **CBK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k201874/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jul 7, 2020
Decision date	Apr 20, 2021
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maquet Critical Care AB</b>
Location	Iselin, NJ, US
Contact	David Ardanius
510(k) history	19 submissions · 19 cleared · 2004-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Getinge</b>
Contact	Mark N Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201874/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026