FDA 510(k) Premarket Notification

CLEARED

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 decision

K201874 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k201874/

SUBMISSION DETAILS

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

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

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