FDA 510(k) Premarket Notification

CLEARED

K230173 Servo-air Lite Ventilator System

Jul 6, 2023
167 days to decision

K230173 · Product code: **MNT** · Anesthesiology
Source: https://www.510kdatabase.net/k230173/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Jan 20, 2023
Decision date	Jul 6, 2023
Days to decision	167 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	Barb Smith

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