

K191027 Flow-i Anesthesia System, Flow-c Anesthesia System, Flow-e Anesthesia System

Mar 18, 2020
335 days to decision

K191027 · Product code: **BSZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k191027/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas-machine, Anesthesia (BSZ)
Date received	Apr 18, 2019
Decision date	Mar 18, 2020
Days to decision	335 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191027/>. Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026