

K192177 SysMed S/TNov 25, 2020
471 days to decisionK192177 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k192177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Aug 12, 2019
Decision date	Nov 25, 2020
Days to decision	471 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmed (China) Co., Ltd.
Location	Shenyang, CN
Contact	Yue Jian
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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