

K213169 BPAP SystemDec 5, 2022
433 days to decisionK213169 · Product code: **MNS** · Anesthesiology
Source: <https://www.510kdatabase.net/k213169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Sep 28, 2021
Decision date	Dec 5, 2022
Days to decision	433 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	BMC Medical Co., Ltd.
Location	Beijing, CN
Contact	Fang Zheng
510(k) history	5 submissions · 5 cleared · 2014-2026

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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