

K203347 Sleep Apnea Breathing Therapy Mask: YF-01 Full Face Mask, YF-02 Full Face Mask, YF-03 Full Face Mask, YN-02 Nasal Mask, YN-03 Nasal Mask, YP-01 Nasal Pillow MaskJul 2, 2021
231 days to decisionK203347 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k203347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 13, 2020
Decision date	Jul 2, 2021
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Yuyue Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Sun Wei
510(k) history	1 submissions · 1 cleared · 2021-2021

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