

K253166 F6S Full Face Mask (F6S)Apr 29, 2026
215 days to decisionK253166 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k253166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 26, 2025
Decision date	Apr 29, 2026
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	P6S Nasal Pillows Interface (P6S)

APPLICANT

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

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