

**K163464 Viva Nasal Mask (Model: NM4), Numa Full Face Mask (Model: BMC-FM2)**

Sep 5, 2017  
270 days to decision

K163464 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k163464/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 9, 2016
Decision date	Sep 5, 2017
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bmc Medical., Ltd.</b>
Location	Haidian, CN
Contact	Jiang Huiqi
510(k) history	1 submissions · 1 cleared · 2017-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k163464/> 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 24, 2026