

**K133009 NASAL MASK, NASAL MASK, FULL FACE MASK**Apr 23, 2014  
210 days to decisionK133009 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k133009/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Sep 25, 2013                                  |
| Decision date         | Apr 23, 2014                                  |
| Days to decision      | 210 days                                      |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>BMC Medical Co., Ltd.</b>          |
| Location       | Beijing, CN                           |
| Contact        | MS. JINJING                           |
| 510(k) history | 5 submissions · 5 cleared · 2014-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133009/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026