

**K252078 BreathePal Bilevel (GFM50-MD2201)**Mar 17, 2026  
258 days to decisionK252078 · Product code: **MNS** · Anesthesiology  
Source: <https://www.510kdatabase.net/k252078/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Jul 2, 2025
Decision date	Mar 17, 2026
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Compal Electronics, Inc.</b>
Location	Taipei, TW
Contact	Casper Chen
Website	<a href="http://www.compal.com">http://www.compal.com</a>
510(k) history	3 submissions · 3 cleared · 2020-2026

Compal Electronics, Inc. is a leading global manufacturer of advanced electronics and computing devices, with a manufacturing facility in Taipei, Taiwan. The company specializes in notebook PCs, LCD products, smart devices, and healthcare technology solutions, serving Fortune 500 companies and emerging startups worldwide. Compal has received FDA 510(k) clearances from total submissions since its first clearance in 2020. The company's cleared devices span multiple medical specialties, including anesthesiology, general and plastic surgery, and radiology. The latest clearanc...