

K103578 PHILIPS NM3 RESPIRATORY MONITOR WITH VENTASSISTJun 2, 2011
178 days to decisionK103578 · Product code: **BZK** · Anesthesiology
Source: <https://www.510kdatabase.net/k103578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Dec 6, 2010
Decision date	Jun 2, 2011
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics Novamatrix, LLC
Location	Wallingford, CT, US
Contact	KEVIN MADER
510(k) history	4 submissions · 4 cleared · 2006-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103578/> 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