

K904396 SIMPLEX NEONATAL BREATHING CIRCUIT SYSTEMMar 5, 1991
161 days to decisionK904396 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k904396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Sep 25, 1990
Decision date	Mar 5, 1991
Days to decision	161 days
Third-party review	No

APPLICANT

Company	Simplex Medical Systems, Inc.
Location	Las Vegas, NV, US
Contact	JAMES WEIGL
510(k) history	3 submissions · 3 cleared · 1991-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904396/>; 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 26, 2026