

K801087 NEONATAL BREATHING CIRCUIT SYSTEMMay 23, 1980
16 days to decisionK801087 · Product code: **BZO** · AnesthesiologySource: <https://www.510kdatabase.net/k801087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing And Support, Ventilator (w Harness) (BZO)
Date received	May 7, 1980
Decision date	May 23, 1980
Days to decision	16 days
Third-party review	No

APPLICANT

Company	Isothermal Systems, Inc.
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1977-1980

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k801087/> 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 28, 2026