

**K922810 ODYSSEY**Jan 22, 1993  
226 days to decisionK922810 · Product code: **BTM** · Anesthesiology  
Source: <https://www.510kdatabase.net/k922810/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jun 10, 1992
Decision date	Jan 22, 1993
Days to decision	226 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>O-Two Systems Intl., Inc.</b>
Location	Walker, MI, US
Contact	KEVIN BOWDEN
510(k) history	14 submissions · 14 cleared · 1983-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922810/> 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