

**K865047 SALTER LABS #4004/4104 OXYGEN MASK W/C02  
SAMP LINE**Feb 10, 1987  
48 days to decisionK865047 · Product code: **BYG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k865047/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Oxygen (BYG)
Date received	Dec 24, 1986
Decision date	Feb 10, 1987
Days to decision	48 days
Third-party review	No

**APPLICANT**

---

Company	<b>Salter Labs</b>
Location	Mchenry, IL, US
Contact	JAMES N CURTI
510(k) history	48 submissions · 48 cleared · 1978-2017

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k865047/>; 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 24, 2026