

K960995 CPR BIO-BARRIER FACESHEILDJan 7, 1997
301 days to decisionK960995 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k960995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	Mar 12, 1996
Decision date	Jan 7, 1997
Days to decision	301 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960995/> 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