

K983643 GENESIS BLSOct 29, 1998
13 days to decisionK983643 · Product code: **BTL** · Anesthesiology
Source: <https://www.510kdatabase.net/k983643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Oct 16, 1998
Decision date	Oct 29, 1998
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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