

K021328 SMART BAG MOJun 26, 2003
426 days to decisionK021328 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k021328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Apr 26, 2002
Decision date	Jun 26, 2003
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	O-Two Systems International, Inc.
Location	Mississauga, CA
Contact	KEVIN BOWDEN
510(k) history	1 submissions · 1 cleared · 2003-2003

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