

K834400 FLYNN III-CHILD BAG-MASK UNIT ETCJan 13, 1984
30 days to decisionK834400 · Product code: **BTM** · AnesthesiologySource: <https://www.510kdatabase.net/k834400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Dec 14, 1983
Decision date	Jan 13, 1984
Days to decision	30 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k834400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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