

K832495 FLYNN SERIES III BAG/MASK UNIT-Sep 29, 1983
64 days to decisionK832495 · Product code: **BTM** · AnesthesiologySource: <https://www.510kdatabase.net/k832495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jul 27, 1983
Decision date	Sep 29, 1983
Days to decision	64 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/k832495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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