

**K982225 SPIRACLE TECHNOLOGY-BI-FLOW
DEMAND/RESUSCITATOR VALVE, MODEL 504**Oct 28, 1998
126 days to decisionK982225 · Product code: **BTL** · Anesthesiology
Source: <https://www.510kdatabase.net/k982225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Jun 24, 1998
Decision date	Oct 28, 1998
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spiracle Technology
Location	Irvine, CA, US
Contact	GUY GANSEL
510(k) history	4 submissions · 4 cleared · 1996-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982225/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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