

K972605 EMS NASAL CPAP MASKJan 28, 1998
201 days to decisionK972605 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k972605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jul 11, 1997
Decision date	Jan 28, 1998
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Engineered Medical Systems
Location	Indianapolis, IN, US
Contact	BONNIE HOLLY
510(k) history	22 submissions · 22 cleared · 1987-2003

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