FDA 510(k) Premarket Notification

K992057 IST RESPONSE MANUAL RESUSCITATOR, MODELS, 008000, 008003,008006

CLEARED

Sep 13, 1999
87 days to decision

K992057 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k992057/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jun 18, 1999
Decision date	Sep 13, 1999
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sims Portex, Inc.**
Location	Keene, NH, US
Contact	TIMOTHY J TALCOTT
510(k) history	12 submissions · 12 cleared · 1998-2001