FDA 510(k) Premarket Notification

K023793 1ST RESPONSE INTERMEDIATE MANUAL RESUSCITATOR

CLEARED

Feb 11, 2003
90 days to decision

K023793 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k023793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Nov 13, 2002
Decision date	Feb 11, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Portex, Inc.**
Location	Walker, MI, US
Contact	CINDY ENGELHARDT
510(k) history	20 submissions · 20 cleared · 1977-2004