FDA 510(k) Premarket Notification

K892885 RESUBMITTED RD1000 NEOPUFF INFANT RESUSCITATOR

CLEARED

Oct 6, 1989
170 days to decision

K892885 · Product code: **BTL** · Anesthesiology
Source: https://www.510kdatabase.net/k892885/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Apr 19, 1989
Decision date	Oct 6, 1989
Days to decision	170 days
Third-party review	No

APPLICANT

Company	**Fisher & Paykel Electronics , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	RICHARD BELGRAVE
510(k) history	17 submissions · 17 cleared · 1988-1998