FDA 510(k) Premarket Notification

K880394 FIRST RESPONSE PEDIATRIC EMERGENCY RESUSCITATOR

CLEARED

Feb 29, 1988
31 days to decision

K880394 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k880394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jan 29, 1988
Decision date	Feb 29, 1988
Days to decision	31 days
Third-party review	No

APPLICANT

Company	**Intertech/Ohio**
Location	Fort Myers, FL, US
Contact	JAMES W POPE
510(k) history	10 submissions · 10 cleared · 1986-1989