FDA 510(k) Premarket Notification

K900577 1ST RESPONSE REUSABLE MANUAL RESUSCITATOR (ADULT)

CLEARED

Jul 16, 1990
159 days to decision

K900577 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k900577/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Feb 7, 1990
Decision date	Jul 16, 1990
Days to decision	159 days
Third-party review	No

APPLICANT

Company	**Intertech Resources, Inc.**
Location	Fort Myers, FL, US
Contact	JAMES W POPE
510(k) history	29 submissions · 27 cleared · 1987-1996