FDA 510(k) Premarket Notification

K970158 BABYPAC

CLEARED

Apr 28, 1998
467 days to decision

K970158 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k970158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jan 16, 1997
Decision date	Apr 28, 1998
Days to decision	467 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Pneupac, Inc.**
Location	Wake Forest, NC, US
Contact	NORMAN GRAY
510(k) history	1 submissions · 1 cleared · 1998-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k970158/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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