FDA 510(k) Premarket Notification

K010317 AV 800 VENTILATOR

CLEARED

Jul 23, 2001
171 days to decision

K010317 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k010317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Feb 2, 2001
Decision date	Jul 23, 2001
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Penlon , Ltd.**
Location	Abingdon Ox, GB
Contact	ANTHONY PARSONS
Website	http://www.penlon.com/en/int/index.html
510(k) history	9 submissions · 9 cleared · 1995-2006