FDA 510(k) Premarket Notification

K960468 DMR/CO2 COMBO KTI

CLEARED

Apr 26, 1996
85 days to decision

K960468 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k960468/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Feb 1, 1996
Decision date	Apr 26, 1996
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nellcor Puritan Bennett, Inc.**
Location	Minneapolis, MN, US
Contact	SHERYLL A MATHEWS
510(k) history	42 submissions · 37 cleared · 1996-2007