FDA 510(k) Premarket Notification

K030822 7600 SERIES MULTI-PATIENT MULTI-USE ORO-NASAL CPAP/NPPV MASKS

CLEARED

Jun 3, 2003
81 days to decision

K030822 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k030822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 14, 2003
Decision date	Jun 3, 2003
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hans Rudolph, Inc.**
Location	Mchenry, IL, US
Contact	KEVIN RUDOLPH
510(k) history	11 submissions · 11 cleared · 1979-2008