FDA 510(k) Premarket Notification

CLEARED

K042455 DEVILBISS NASAL CPAP MASK, 9354 SERIES

Jan 14, 2005
126 days to decision

K042455 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k042455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 10, 2004
Decision date	Jan 14, 2005
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunrise Medical**
Location	Somerset, PA, US
Contact	ALLAN JONES
Website	http://www.sunrisemedical.co.uk/
510(k) history	14 submissions · 14 cleared · 2002-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k042455/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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