FDA 510(k) Premarket Notification

K093070 DEVILBISS INTELLIPAP/ SLEEPCUBE BILEVEL ST, DV56 ST SERIES

CLEARED

Jan 26, 2010
118 days to decision

K093070 · Product code: **MNS** · Anesthesiology
Source: https://www.510kdatabase.net/k093070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Sep 30, 2009
Decision date	Jan 26, 2010
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunrise Medical**
Location	Somerset, PA, US
Contact	BETTY LOU MILLER
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/k093070/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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