FDA 510(k) Premarket Notification

K173367 MC 300* Nebulizer

CLEARED

Feb 28, 2018
125 days to decision

K173367 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k173367/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Oct 26, 2017
Decision date	Feb 28, 2018
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trudell Medical International**
Location	London, CA
Contact	Marianne Tanton
510(k) history	9 submissions · 9 cleared · 2015-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k173367/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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