FDA 510(k) Premarket Notification

# K141140 COMP A-I-R

**CLEARED**

Sep 30, 2014
151 days to decision

K141140 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k141140/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received | May 2, 2014 |
| Decision date | Sep 30, 2014 |
| Days to decision | 151 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Omron Healthcare, Inc.** |
| Location | Vernon Hills, IL, US |
| Contact | PAUL DRYDEN |
| 510(k) history | 68 submissions · 67 cleared · 1991-2024 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141140/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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