FDA 510(k) Premarket Notification

K150365 Cloud9 System

CLEARED

Jul 21, 2015
159 days to decision

K150365 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k150365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 12, 2015
Decision date	Jul 21, 2015
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Insleep Technologies, LLC**
Location	Eden Prairie, MN, US
Contact	Marty Kerber
510(k) history	1 submissions · 1 cleared · 2015-2015