FDA 510(k) Premarket Notification

K083050 EVITE XL

CLEARED

Dec 29, 2008
76 days to decision

K083050 · Product code: **CBK** · Anesthesiology
Source: https://www.510kdatabase.net/k083050/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Oct 14, 2008
Decision date	Dec 29, 2008
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Draeger Medical AG & Co. KG**
Location	Telford, PA, US
Contact	JOYCE KILROY
510(k) history	10 submissions · 10 cleared · 2008-2010

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k083050/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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