

**K093632 INFINITY ACUTE CARE SYSTEM WORKSTATION
NEONATAL CARE**Apr 5, 2010
133 days to decisionK093632 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k093632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Nov 23, 2009
Decision date	Apr 5, 2010
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Drager Medical AG & Co. KgaA
Location	Telford, PA, US
Contact	JOYCE KILROY
510(k) history	3 submissions · 3 cleared · 2005-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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