

K050597 GE DATEX-OHMEDA ENGSTROM CARESTATIONMar 25, 2005
16 days to decisionK050597 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k050597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Mar 9, 2005
Decision date	Mar 25, 2005
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datex-Ohmeda, Inc.
Location	Madison, WI, US
Contact	DAN KOSEDNAR
510(k) history	60 submissions · 60 cleared · 1998-2025

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