

K140575 ENGSTROM CARESTATION, ENGSTROM PROFeb 3, 2015
334 days to decisionK140575 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k140575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Mar 6, 2014
Decision date	Feb 3, 2015
Days to decision	334 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026