

K041524 GE DATEX-OHMEDA HELIOX DELIVERY SYSTEMSep 20, 2004
104 days to decisionK041524 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k041524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Jun 8, 2004
Decision date	Sep 20, 2004
Days to decision	104 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041524/> 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 24, 2026