

**K111116 ENGSTROM CARESTATION, ENGSTROM PRO,
MODELS 1505-9000-000, 1505-9003-000**Sep 9, 2011
141 days to decisionK111116 · Product code: **CBK** · Anesthesiology
Source: <https://www.510kdatabase.net/k111116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Facility Use (CBK)
Date received	Apr 21, 2011
Decision date	Sep 9, 2011
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Datex-Ohmeda
Location	Tewksbury, MA, US
Contact	MONICA MORRISON
510(k) history	41 submissions · 41 cleared · 2000-2023

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