

K183394 CARESCAPE Respiratory Modules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO

May 1, 2019
145 days to decision

K183394 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k183394/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Dec 7, 2018
Decision date	May 1, 2019
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Healthcare Finland Oy
Location	Madison, WI, US
Contact	Joel Kent
510(k) history	30 submissions · 30 cleared · 2007-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183394/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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