

K171028 CARESCAPE Respiratory MOdules, E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX and accessoriesAug 17, 2017
134 days to decisionK171028 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k171028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Apr 5, 2017
Decision date	Aug 17, 2017
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171028/> 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