

K220533 Endoscopy Oxygen MaskNov 16, 2022
265 days to decisionK220533 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k220533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Feb 24, 2022
Decision date	Nov 16, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Engineered Medical Systems, Inc.
Location	Bonita Springs, FL, US
Contact	Tamara Lefevers
510(k) history	2 submissions · 2 cleared · 2007-2022

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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