FDA 510(k) Premarket Notification

K190561 NICU V'02

CLEARED

Sep 4, 2020
549 days to decision

K190561 · Product code: **BZL** · Anesthesiology
Source: https://www.510kdatabase.net/k190561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Oxygen-uptake (BZL)
Date received	Mar 5, 2019
Decision date	Sep 4, 2020
Days to decision	549 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cosmed Nordic Aps**
Location	Odense, DK
Contact	Peter Clemensen
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Wood Burditt Group**
Contact	H. Carl Jenkins

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