

K161411 Care Cycle Connect Application

Feb 17, 2017
273 days to decision

K161411 · Product code: **MOD** · Anesthesiology
Source: <https://www.510kdatabase.net/k161411/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory To Continuous Ventilator (respirator) (MOD)
Date received	May 20, 2016
Decision date	Feb 17, 2017
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	Colleen Witt
Website	https://www.respironics.com
510(k) history	172 submissions · 168 cleared · 1977-2024

Respironics, Inc. is an American medical supply company owned by Philips. It specializes in products that improve respiratory functions and is based in Monroeville, Pennsylvania. The company maintains a strong FDA 510(k) regulatory record spanning from 1977 to 2024. Respironics has received FDA 510(k) clearances from total submissions. The dominant focus is Anesthesiology devices, which represent approximately 90% of all submissions. The latest clearance in 2024 reflects continued regulatory activity. Recent cleared devices include masks, ventilators, and sleep therapy sy...