

K142988 Sleepware G3Mar 16, 2015
151 days to decisionK142988 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k142988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Oct 16, 2014
Decision date	Mar 16, 2015
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	DANIELA AIZPITARTE
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...
