

K010052 RESPIRONICS BILICHEK NON-INVASIVE-100-0800-20Mar 19, 2001
70 days to decisionK010052 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k010052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Jan 8, 2001
Decision date	Mar 19, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary
Other names	BILIRUBIN ANALYZER

APPLICANT

Company	Respironics, Inc.
Location	Monroeville, PA, US
Contact	DAVID J VANELLA
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...