

# K821384 EXERCISE ECG ELECTRODES, REUSABLE

Jun 17, 1982  
38 days to decision

K821384 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k821384/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	May 10, 1982
Decision date	Jun 17, 1982
Days to decision	38 days
Third-party review	No

## APPLICANT

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Company	<b>Respironics, Inc.</b>
Location	Monroeville, PA, US
Website	<a href="https://www.respironics.com">https://www.respironics.com</a>
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...