

**K770038 MONITOR, HEARTWATCH HEART RATE**Jan 14, 1977  
4 days to decisionK770038 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k770038/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jan 10, 1977
Decision date	Jan 14, 1977
Days to decision	4 days
Third-party review	No

**APPLICANT**

---

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...

---