

**K082465 EVERON**Mar 25, 2009  
210 days to decisionK082465 · Product code: **BZQ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k082465/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Aug 27, 2008
Decision date	Mar 25, 2009
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Earlysense, Ltd.</b>
Location	Tel Aviv, IL
Contact	DALIA ARGAMAN
Website	earlysense.com
510(k) history	12 submissions · 12 cleared · 2007-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026