

K131379 EARLYSENSEDec 18, 2013
218 days to decisionK131379 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k131379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	May 14, 2013
Decision date	Dec 18, 2013
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k131379/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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