

K152911 EarlySense Insight SytemMay 6, 2016
217 days to decisionK152911 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k152911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Oct 2, 2015
Decision date	May 6, 2016
Days to decision	217 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.netDevice record: <https://www.510kdatabase.net/k152911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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