

K120465 EARLYSENSE (EVERON) SYSTEMJun 8, 2012
114 days to decisionK120465 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k120465/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Breathing Frequency (BZQ) |
| Date received | Feb 15, 2012 |
| Decision date | Jun 8, 2012 |
| Days to decision | 114 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/k120465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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