

**K121885 EARLYSENSE CENTRAL DISPLAY SYSTEM**Sep 10, 2012  
74 days to decisionK121885 · Product code: **MSX** · CardiovascularSource: <https://www.510kdatabase.net/k121885/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Special   |
| Device classification | System, Network And Communication, Physiological Monitors (MSX) |
| Date received         | Jun 28, 2012  |
| Decision date         | Sep 10, 2012  |
| Days to decision      | 74 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121885/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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