

**K170463 KetoSens Blood B-Ketone Monitoring System,  
KetoSens Multi Blood B-Ketone Monitoring System**Apr 13, 2018  
422 days to decisionK170463 · Product code: JIN · Chemistry  
Source: <https://www.510kdatabase.net/k170463/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Nitroprusside, Ketones (urinary, Non-quant.) (JIN) |
| Date received         | Feb 15, 2017                                       |
| Decision date         | Apr 13, 2018                                       |
| Days to decision      | 422 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>I-Sens, Inc.</b>                     |
| Location       | Seoul, KR                               |
| Contact        | Joon Ho Jung                            |
| 510(k) history | 27 submissions · 27 cleared · 2008-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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