

**K201551 KetoSens BT Blood B-Ketone Monitoring System**Sep 9, 2020  
92 days to decisionK201551 · Product code: **JIN** · Chemistry  
Source: <https://www.510kdatabase.net/k201551/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nitroprusside, Ketones (urinary, Non-quant.) (JIN)
Date received	Jun 9, 2020
Decision date	Sep 9, 2020
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**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/k201551/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026