

**K181201 Synermed ISE Reagents**Jul 10, 2018  
64 days to decisionK181201 · Product code: **JGS** · Chemistry  
Source: <https://www.510kdatabase.net/k181201/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	May 7, 2018
Decision date	Jul 10, 2018
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infrared Laboratory Systems, LLC (Dbas Synermed)</b>
Location	Westfield, IN, US
Contact	Julie Paschal
510(k) history	3 submissions · 3 cleared · 2016-2018

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