

**K153692 Synermed Glucose Reagent, Synermed IR-1200  
Chemistry Analyzer**

Jun 24, 2016  
184 days to decision

K153692 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k153692/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 23, 2015
Decision date	Jun 24, 2016
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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