

**K183255 Coag-Sense Prothrombin Time (PT) / INR Monitoring Device**Feb 21, 2019  
92 days to decisionK183255 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k183255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Nov 21, 2018
Decision date	Feb 21, 2019
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coagusense, Inc.</b>
Location	Fremont, CA, US
Contact	Robin Bush
510(k) history	3 submissions · 3 cleared · 2010-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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