

**K122162 AGGREGUIDE**Dec 20, 2013  
518 days to decisionK122162 · Product code: **JOZ** · Hematology  
Source: <https://www.510kdatabase.net/k122162/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Jul 20, 2012
Decision date	Dec 20, 2013
Days to decision	518 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>AggreDyne, Inc.</b>
Location	Houston, TX, US
Contact	J. HARBEY KNAUSS
510(k) history	3 submissions · 3 cleared · 2013-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122162/> 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 June 19, 2026