

K163274 AggreGuide A-100 AA Assay, AggreGuide A-100 InstrumentApr 5, 2017
135 days to decisionK163274 · Product code: **JOZ** · Hematology
Source: <https://www.510kdatabase.net/k163274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Nov 21, 2016
Decision date	Apr 5, 2017
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AggreDyne, Inc.
Location	Houston, TX, US
Contact	Philip C. Speros
510(k) history	3 submissions · 3 cleared · 2013-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163274/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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