

K181777 AggreGuide A-100 ADPMar 29, 2019
269 days to decisionK181777 · Product code: **JOZ** · Hematology
Source: <https://www.510kdatabase.net/k181777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Automated Platelet Aggregation (JOZ)
Date received	Jul 3, 2018
Decision date	Mar 29, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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