March 29, 2019

Aggredyne, Inc.
Philip Speros, COO
10530 Rockley Road, Suite 150
Houston, Texas 77099

Re: K181777
Trade/Device Name: AggreGuide A-100 ADP
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: Class II
Product Code: JOZ
Dated: June 29, 2018
Received: July 3, 2018

Dear Philip Speros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K181777

Device Name
AggreGuide A-100 ADP Assay

Indications for Use *(Describe)*

The AggreGuide A-100 ADP Assay is used with the AggreGuide A-100 instrument in non-CLIA waived physician's office or clinical laboratory for the detection of platelet dysfunction in patients age 22 or older receiving P2Y12 antiplatelet drugs, prasugrel and ticagrelor, using 3.2% sodium citrated whole blood. The AggreGuide A-100 ADP Assay is a semi-quantitative assay. The level of platelet aggregation is determined by the platelet activity index (PAI) where values < 4.7 PAI suggest that platelet dysfunction is due to the presence of P2Y12 antiplatelet drugs, prasugrel and ticagrelor. The test results should be interpreted in conjunction with all other clinical and laboratory data available to the clinician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary—K181777

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Aggredyne, Inc., AggreGuide A-100 ADP Assay.

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1. Company making the submission:

Name:	Aggredyne, Inc.
Address:	10530 Rockley Road Suite 150 Houston, Texas 77099
Telephone:	713-636-5996
Contact:	Phil Speros
E-Mail:	psperos@aggredyne.com

2. Device Name:

Trade/Proprietary Name:	AggreGuide A-100 ADP Assay
Common/Usual Name:	ADP platelet function test
Classification Name:	System automated platelet aggregation
Regulation Number:	864.5700
Product Code:	JOZ
Class	II

3. Predicate Devices:

The predicate is:

VerifyNow-P2Y12 Assay [K141427]

4. Description of Device:

The AggreGuide A-100 ADP Assay is an individual use, disposable assay cartridge for use with the AggreGuide A-100 instrument. The cartridge contains preloaded freeze dried agonist. The level of platelet aggregation induced by the adenosine diphosphate (ADP) agonist in a sample of whole blood is detected within the cartridge. The amount of platelet aggregation is measured by detecting and quantifying the laser light scattering caused by platelet aggregates. P2Y12 inhibitor drugs e.g. clopidogrel, prasugrel, and ticagrelor are known to inhibit the level of platelet aggregation, causing platelet dysfunction.

5. Intended Use Statement:

The AggreGuide A-100 ADP Assay is used with the AggreGuide A-100 instrument in non-CLIA waived physician's office or clinical laboratory for the detection of platelet dysfunction in patients age 22 or older receiving P2Y12 antiplatelet drugs, prasugrel and ticagrelor, using 3.2% sodium citrated whole blood. The AggreGuide A-100 ADP Assay is a semi-quantitative assay. The level of platelet aggregation is determined by the platelet activity index (PAI) where values < 4.7 PAI suggest that platelet dysfunction is due to the presence of P2Y12 antiplatelet drugs, prasugrel and ticagrelor. The test results should be interpreted in conjunction with all other clinical and laboratory data available to the clinician.

6. Summary of the technological characteristics of the device compared to predicate device:

The AggreGuide A-100 ADP Assay and VerifyNow® PRUTest, each measure platelet aggregation in response to ADP. In the presence of ADP, platelets may be activated and aggregate. In both the AggreGuide A-100 and the VerifyNow® the ADP reagent is freeze dried and pre-loaded into disposable, single use cartridges. The AggreGuide A-100 ADP Assay detects platelet aggregates in whole blood as they pass by the optical window by detecting and quantifying light scattering. The VerifyNow® detects platelet aggregation at its optical window by measuring light transmittance. With the AggreGuide, the more active the platelets, the more aggregates are formed and the higher the Platelet Activity Index (PAI). With the VerifyNow®, the more active the platelets, the more light transmittance and the higher the P2Y12 Reactive Units (PRU). Conversely, if the platelets are inhibited by P2Y12 inhibitor drugs, they are not activated by ADP to form aggregates. Therefore, few, if any, aggregates form and the AggreGuide reports a low PAI, and, similarly, the VerifyNow® reports a low PRU. The AggreGuide's PAI, like the VerifyNow's® PRU, is a function of the level of platelet aggregate formation in whole blood.

7. Performance Testing:

Non-clinical testing: Precision, shelf life of the ADP reagent, sample stability, in-use stability, shipping stability, interfering substances, limit of blank (LOB), and lot-to-lot variability tests were carried out. These studies showed that the AggreGuide A-100 ADP Assay raised no safety concerns when used according to the Instructions for Use.

Clinical Testing:

Specificity of the AggreGuide A-100 ADP Assay is 0.907**.**

Sensitivity of the AggreGuide A-100 ADP Assay as evaluated against a clinical truth data set comprising off -therapy (baseline) versus on-therapy with P2Y12 inhibitor medications. On-therapy clinical truth utilized high potency P2Y12 medications at a time of full- effect. Sensitivity values are shown in this table:

Sensitivity

High Potency P2Y12 Inhibitors at Peak Effect

Stratified by Dose Status

with Exact Confidence Intervals

Study Anti-Platelet Drug	**N**	**Timing** Data point name (time from dose)	**PAI (A-100)** **(95% CI Limits)**	**PRU (VerifyNow)** **(95% CI Limits)**	**Pre-Specified SENSITIVITY Acceptance Criteria**
Prasugrel	43	**Post-Loading** (24 hours)	1.000 (0.918 – 1.000)	0.977 (0.877 – 0.996)	≥ 0.80
	43	**Post-Maintenance** (7 days)	0.907 (0.784 – 0.963)	0.977 (0.877 – 0.996)	≥ 0.80
Ticagrelor	85	**Post-Loading** (3 – 6 hours)	0.906 (0.825 – 0.952)	1.000 (0. 957– 1.000)	≥ 0.80
	143	**Post-Maintenance** (7 days)	0.839 (0.770 – 0.890)	0.986 (0.951 – 0.998)	≥ 0.80

Cut Off Point is confirmed by ROC Decision Threshold / J-statistic (Youden) analysis of the clinical truth data set.

The combination of non-clinical and clinical performance test results shows that the AggreGuide ADP Assay performs in a substantially equivalent manner to the predicate.

8. The AggreGuide A-100 ADP Assay is a prescription device per 21 CFR Subpart D.

9. Conclusion:

The AggreGuide A-100 AA Assay is substantially equivalent to the predicate devices based on intended use, technology and performance testing results.

Aggredyne, Inc.

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Philip C. Speros
Chief Operating Officer