DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 5, 2017

Aggredyne, Inc.
Mr. Philip C. Speros
Chief Operating Officer
10530 Rockley Road
Houston, Texas 77099

Re: K163274
Trade Name: AggreGuide A-100 AA Assay, AggreGuide A-100 Instrument
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: Class II
Product Code: JOZ
Dated: November 18, 2016
Received: November 21, 2016

Dear Mr. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/ Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Lea Carrington, MS, MBA, MT(ASCP)
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)*
K163274

Device Name
AggreGuide A-100 AA assay
AggreGuide A-100 Instrument

Indications for Use *(Describe)*
The AggreGuide A-100 AA Assay is a qualitative system to aid in the detection of platelet dysfunction due to aspirin ingestion by those 18 years of age or older in 3.2% citrated venous whole blood using the AggreGuide A-100 instrument. For professional use. This test is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents. The test results should be interpreted in conjunction with 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92(c).

1. **Submitter**

Name:	Aggredyne, Inc.
Address:	10530 Rockley Road Suite 150 Houston, TX 99077
Phone:	713-636-5996 866-800-1955
Contact:	Philip Speros, Ph.D. psperos@aggredyne.com

2. **Device**

Trade Name(s):	AggreGuide A-100 AA assay AggreGuide A-100 Instrument
Common Name:	Platelet aggregation test

The AggreGuide A-100 AA assay and AggreGuide A-100 Instrument are classified as Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for automated platelet aggregation test systems.

Product Code:	JOZ
Regulation Number:	21 CFR 864.5700
Classification Name:	System, Automated Platelet Aggregation

3. **Predicate Device**

The predicate device(s) used for the determination of substantial equivalence are the previously-cleared AggreGuide A-100 AA assay and AggreGuide A-100 Instrument, 510(k) document number K122162.

4. **Device Description**

The AggreGuide A-100 is a laser light scattering system that detects the level of platelet aggregation induced by arachidonic acid agonist in whole blood in motion. The system consists of an instrument and a disposable assay cartridge with pre-loaded freeze dried agonist. A whole blood sample is added to a disposable cartridge that is preloaded with freeze dried arachidonic acid agonist (AA) in a reaction chamber for an individual test. The amount of platelet aggregation is measured by detecting the laser light scattering caused by platelet aggregates. Aspirin is known to inhibit the level of platelet aggregation, or activity, when blood is mixed with arachidonic acid.

5. **Indications for Use**

The AggreGuide A-100 AA Assay is a qualitative system to aid in the detection of platelet dysfunction due to aspirin ingestion by those 18 years of age or older in 3.2% citrated venous whole blood using the AggreGuide A-100 instrument. For professional use. This test is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents. The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.

6. Comparison with Predicate Device

The predicate device(s) used for the determination of substantial equivalence are the previously-cleared AggreGuide A-100 AA assay and AggreGuide A-100 Instrument, 510(k) document number K122162.

Item	Predicate Device (K122162)	Current Device
Device Name	AggreGuide A-100	Same
Regulation Number	864.5700	Same
Product Code	JOZ	Same
Principle of Operation	Platelet aggregation with detection of laser light scattering	Same
Indications for Use	The AggreGuide A-100 AA Assay is a qualitative system to aid in the detection of platelet dysfunction due to aspirin ingestion by those 18 years of age or older in 3.2% citrated venous whole blood using the AggreGuide A-100 instrument. For professional use. This test is not for use in patients with underlying congenital platelet abnormalities, patients with non-aspirin induced acquired platelet abnormalities or in patients receiving non-aspirin anti-platelet agents. The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.	Same
Intended Use	The AggreGuide device is intended for patients for whom detecting platelet dysfunction in response to arachidonic acid may be desirable, such as those who are on or are candidates for antiplatelet therapy.	Same
Specimen Type	3.2% sodium citrate-anticoagulated whole blood	Same
Test Cartridges	Single-use disposable	Same
Agonist Concentration Used for Platelet Activation	Arachidonic Acid, 1 mM	Same
Test Procedure	Manual addition of blood sample to test cartridge, automated assay and generation of results	Same
Time to Result	5 minutes	Same
Sample Volume Required	164 µL	Same
Results Displayed	Platelet Activity Index (PAI)	Same
Calibration	Performed at Factory	Same
Sterility	Not sterile	Same
Laser Diode Part	**Sanyo DL-4140-001S**	**QSI QL7816SA-L**
Quality Control Cartridge	**QC quality control cartridge for instrument self-check**	**Modified quality control QC2 cartridge**
Software	**Version 4.91**	**Version 5.10**
Test Cartridge Shelf Life	**12 months**	**18months**
User's Manual	**LBL-0014-C**	**LBL-0014-E**

7. Summary of Performance Data

The risk analysis method used to assess the impact of the modifications was ISO 14971:2007, "Medical devices -- Application of risk management to medical devices".

Additional modification-specific criteria were applied to each modification as necessary and as noted in the body of the 510(k).

The results of the laser diode part replacement verification and validation activities demonstrated acceptable performance.

The results of the QC2 implementation process and verification and validation activities demonstrated acceptable performance.

The results of software and design verification and validation activities demonstrated acceptable performance.

The results from stability testing using an isochronous testing paradigm supported the shelf-life extension to 18 months based on acceptance criteria of ±1 PAI unit.

The results of User's Manual revision activities showed acceptable validation and verification results.

8. Conclusions

The modified AggreGuide A-100 AA assay and AggreGuide A-100 Instrument have the following similarities to those which previously received 510(k) clearance:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic design,
- incorporate the same reagents, and
- are packaged using the same materials and processes.

The modifications did not require collection of clinical performance data. In addition, the results of design verification and validation tests do not raise new issues of safety and effectiveness.

In summary, the AggreGuide A-100 AA assay and AggreGuide A-100 Instrument described in this submission are, in our opinion, substantially equivalent to the predicate device.