K990398

DEC - 1 1999

510(k) Summary of Safety and Effectiveness Information
Plateletworks™ Platelet Aggregation Assay

Array Medical, Inc.
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(908)707-8872

Contact: David Carville, Ph.D., (908)707-8872; (219)237-4829

Date: June 25, 1999

Device Names:

Trade Name: Plateletworks

Common Name: Platelet Aggregation Assay

Classification Name: System, Automatic Platelet Aggregation

Legally Marketed Device:

Sigma Platelet Aggregation Reagents, K822733, K832929

Chrono-log Platelet Aggregometer, K77198, K830749, K851025

Device Description:

Plateletworks is a unitized screening assay for determining platelet aggregation in a whole blood sample using the Ichor hematology analyzer. The Plateletworks methodology is an adaptation of platelet aggregometry that is extremely simple, inexpensive, and quick to perform (results are available in about five minutes). This method involves using the Ichor hematology analyzer (based on electronic impedance principles) to measure total platelet count in a whole blood sample and then to redetermine the number of platelets in a second sample that has been exposed to a known platelet agonist. The agonist will stimulate those platelets which are functional to aggregate into clumps, and they will not be counted as platelets in the second sample. The difference in platelet counts between samples one and two provides a direct measurement of platelet aggregation and is reported as percent aggregation as per the following equation:

$$\frac{\text{Baseline Platelet Count} - \text{Agonist Platelet Count}}{\text{Baseline Platelet Count}} \times 100 = \% \text{ Aggregation}$$

Intended Use:

Plateletworks is an in vitro diagnostic screening assay for the determination of % platelet aggregation in fresh whole blood samples taken during cardiac interventional procedures; as measured by a change in platelet count due to activation of functional platelets and is designed for use on the Ichor™ hematology analyzer.

Comparison with Predicate Device:

The Plateletworks Platelet Aggregation Assay is substantially equivalent to Sigma platelet aggregation reagents, previously cleared under Document Control # K822733 and K832929, used on the Chrono-log Platelet Aggregometer (Model 560-VS), previously cleared under Document Control # K771198, K830749 and K851025. These products are currently in commercial distribution by Sigma Diagnostics, St. Louis, MO and Chrono-log Corporation, Havertown, PA, respectively.

Substantial Equivalence:

Correlation of the Plateletworks assay to platelet aggregometry on platelet rich plasma (PRP) is supported by data generated by testing male and female adults, between the ages of 18 and 85, at three clinical sites. This includes healthy volunteers, patients undergoing cardiopulmonary bypass surgery, and patients undergoing cardiac catheterization.

All blood samples, for performing both Plateletworks assays and PRP aggregometry, were acquired from in-dwelling lines or venipuncture using established methods. For performing both the Plateletworks assays and PRP aggregometry, the manufacturers' recommendations were adhered to as per instructions provided in the package insert for each test system.

Regression analysis (correlation coefficients) was performed to assess the agreement between the two methods (i.e., Plateletworks and PRP aggregometry). Positive correlations were demonstrated for each agonist tested (ADP and collagen). See Figures 1 and 2

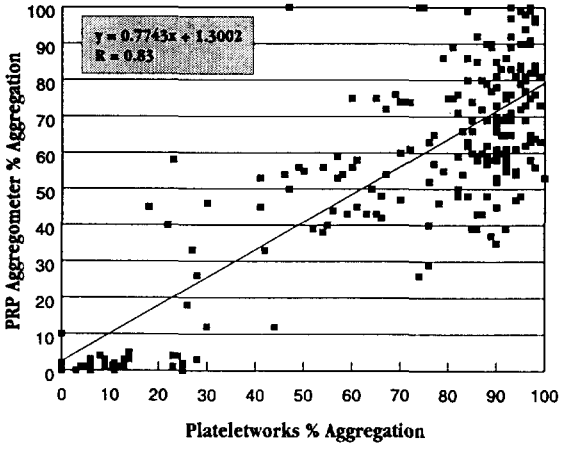

Figure 1. ADP

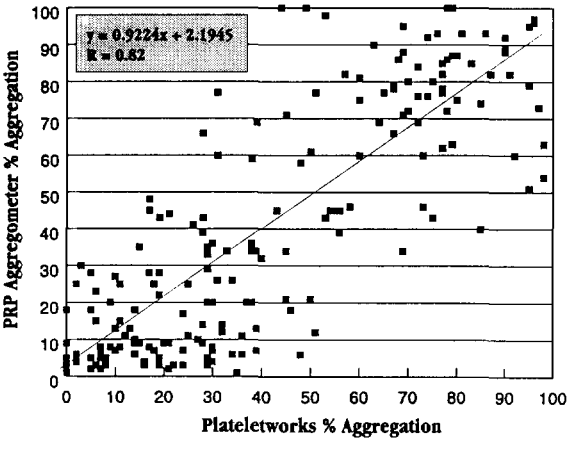

Figure 2. Collagen

However, it is recognized that correlation coefficients measure the strength of the relationship between the methods and not the agreement between them (*Bland JM, Altman DG: Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;Feb:307-310.*) Further, since the data for both aggregation systems are bounded by 100% as the upper limit of aggregation, regression analysis is not expected to describe a predictive relationship. Therefore, the data from the clinical sites where substantial equivalence testing was performed were also subjected to the non-parametric analyses of both Kendall Tau and Spearman Rho which "test for a positive correlation without specifying linearity". The results from these analyses are shown (with the regression analysis).

Comparative Data: Plateletworks vs. PRP Aggregometry

	N	(Pearson) r	Spearman Rho	Kendall Tau
Collagen	189	0.82*	0.80*	0.58*
ADP	225	0.83*	0.68*	0.50*

*P<0.001 two-sided test of positive association significant

These data support the use of the Plateletworks assay to measure platelet aggregation in the clinical setting (near-patient testing).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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David Carville, Ph.D.
Vice President, New Product Development
Array Medical, Inc.
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Somerville, New Jersey 08876

Re: K990398
Trade Name: Plateletworks™
Regulatory Class: II
Product Code: JOZ
Dated: September 3, 1999
Received: September 15, 1999

Dear Dr. Carville:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K990398

Device Name: Plateletworks™

Indications for Use:

Plateletworks is an in vitro diagnostic screening assay for the determination of % platelet aggregation in fresh whole blood samples taken during cardiac interventional procedures as measured by a change in platelet count due to activation of functional platelets. It may be used at the point-of-care on the Ichor hematology analyzer as a screening tool for the detection of trends suggestive of platelet dysfunction. Any abnormal baseline or otherwise suspicious result would require repeating the Plateletworks test procedure and/or further additional investigation with more definitive test methods, including conventional platelet aggregometry.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D Market

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990398

Prescription ✓

(Optional Format 3-10-98)

(Posted July 1, 1998)