K 05123/

AUG 5 - 2005

**510(k) Summary**

**Accumetrics Verify*Now* P2Y12**

Accumetrics
3985 Sorrento Valley Blvd.
San Diego, CA 92121

July 29, 2005

For information regarding this 510(k) Summary, please contact Accumetrics, Barbara Stevens (858) 404-8281.

Device Names:

Trade Name: Verify*Now*-P2Y12 Assay

Common Name: Verify*Now*-P2Y12 Assay Devices
Verify*Now* Assay Wet Controls, Levels 1 and 2
Verify*Now* Instrument
Verify*Now* Electronic Control

Classification Name:
System, Automated Platelet Aggregation
21 CFR 864.5700
81 JOZ
Hematology Panel

Accumetrics is claiming substantial equivalence of the Verify*Now*-P2Y12 Assay to other currently marketed, automated aggregation devices, specifically the CHRONO-LOG Whole Blood Aggregometer with CHRONO-PAR® ADP Reagent, as the predicate device. The CHRONO-LOG Whole Blood Aggregometer was cleared under k830749.

Device Description:
The Verify*Now* System is a turbidimetric based optical detection system, which measures platelet induced aggregation as an increase in light transmittance. The system consists of a stand-alone instrument and disposable assay device with reagents based on microbead agglutination technology. The quality control system includes an electronic control, an assay device internal control, and two levels of liquid control. The instrument controls assay sequencing, establishes the assay temperature, controls the reagent-sample mixing for the required duration, determines the degree of platelet function, displays the results and status information to the user, and performs self-diagnostics.

The assay device contains a lyophilized preparation of human fibrinogen coated beads, adenosine-5-diphosphate (ADP), a peptide, a fatty acid, buffer, and preservative. The patient sample is citrated whole blood, which is automatically dispensed from the blood collection tube into the assay device by the instrument, with no blood handling required by the user.

Fibrinogen-coated microparticles are used in the Verify*Now*-P2Y12 assay device to bind activated platelet GP IIb/IIIa receptors. ADP is incorporated into the assay to activate platelets, and the reagent is formulated to specifically measure P2Y12 – mediated platelet aggregation.

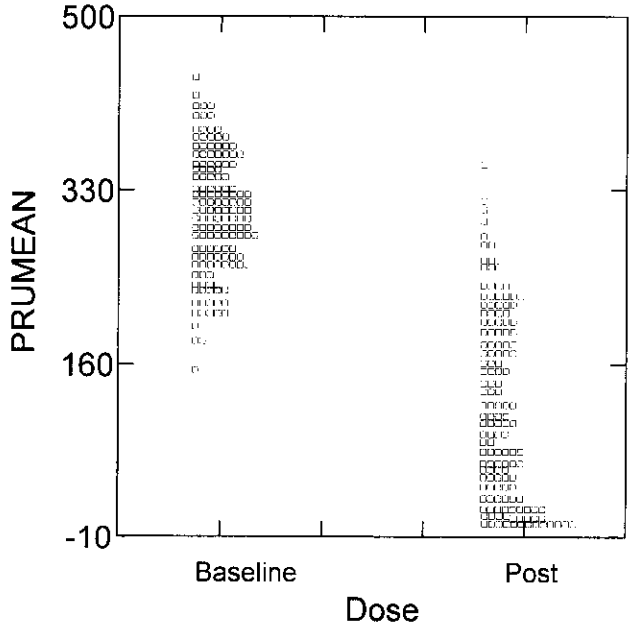
When the activated platelets are exposed to the fibrinogen-coated microparticles, aggregation occurs in proportion to the number of activated platelet receptors. The Verify*Now*-P2Y12 Assay reports results in P2Y12 Reaction Units (PRU).

Intended Use:
The Verify*Now*-P2Y12 Assay is a whole blood assay used in the laboratory or point of care setting to measure the level of platelet P2Y12 receptor blockade.

Technological Characteristics:
The Verify*Now*-P2Y12 Assay is similar to the CHRONO-LOG Optical Aggregometer in that it employs an optical measurement method. Whereas the CHRONO-LOG Whole Blood Aggregometer measures impedance, it has been found to be substantially equivalent to the optical detection version of the aggregometer. The Verify*Now*-P2Y12 Assay is similar to the CHRONO-LOG Whole Blood Aggregometer in that it uses citrated, whole blood samples and measures platelet aggregation. The Verify*Now*-P2Y12 Assay adds the use of fibrinogen-coated microparticles, which are not used in the CHRONO-LOG aggregometry methods.

Performance Characteristics:
The VerifyNow P2Y12 Assay was evaluated in patients treated with clopidogrel, a drug known to specifically block the platelet P2Y12 ADP receptor. The VerifyNow Assay was compared to platelet aggregometry using a CHRONO-LOG Optical Aggregometer (Light Transmittance Aggregometry - LTA) with 5 μM ADP as the agonist. Testing was performed in clinical studies at 4 centers on 147 subjects with a history of vascular disease or risk factors

The following vertical histogram shows the distribution of PRU values in patients before and after clopidogrel administration. The figure demonstrates a clear separation in the subjects' baseline and their post-clopidogrel P2Y12 assay values. The VerifyNow-P2Y12 Assay measured changes in PRU ranging from a minimum of 18 PRU to a maximum of 435 PRU with a mean change of 185 PRU.



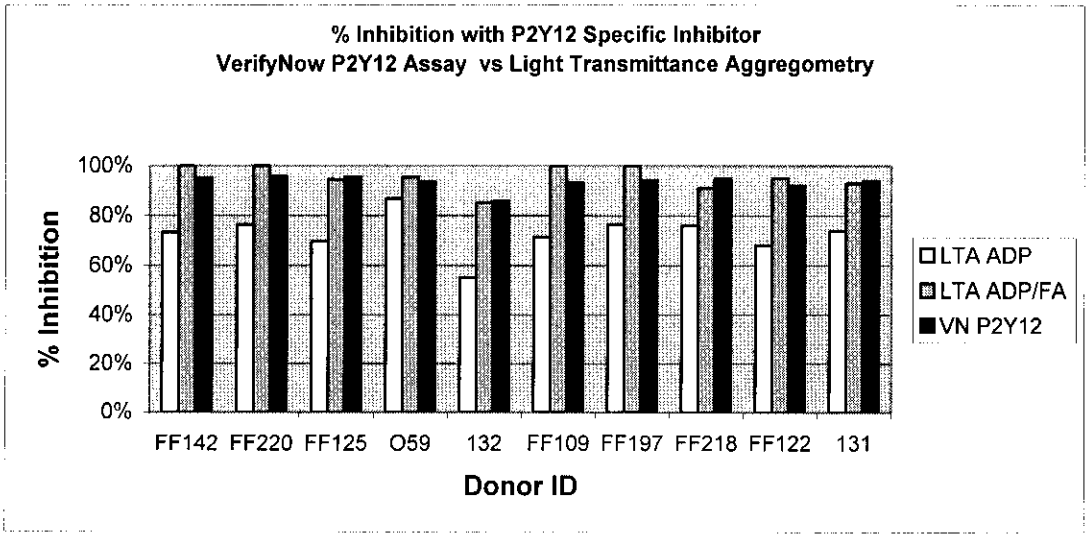
A reference range for the VerifyNow-P2Y12 Assay was calculated at the 95% confidence level for the baseline (pre-clopidogrel) dataset, using NCCLS Guideline C28-A2. This is summarized in the following table.

| | |
|---|---|
| **n** | 147 |
| **Mean** | 306.7 |
| **SD** | 58.5 |
| **Reference Range** | 194 - 418 |

The VerifyNow-P2Y12 Assay is formulated to be specific to aggregation mediated by only the P2Y12 receptor, whereas in LTA, using ADP as the agonist, aggregation results are affected by both platelet ADP receptors - P2Y1 and P2Y12. Since clopidogrel acts only on the P2Y12 receptor site, LTA has a non-specific aggregation artifact due to P2Y1 mediated aggregation that is not seen in the Verify*Now*-P2Y12 Assay. In order to compare the clinical PRU and LTA results, post-clopidogrel data are expressed as percent inhibition, or percent reduction from baseline.

To accomplish the goal of having an assay with reduced non-specific aggregation, the *VerifyNow* P2Y12 assay uses an additive (a fatty acid) in addition to ADP to make the assay more sensitive and specific for the effects of ADP mediated by the P2Y12 receptor.

The following data illustrate the effect of the additive on LTA assay specificity to the P2Y12 receptor. Blood was drawn from 10 individuals, and a known specific P2Y12 inhibitor, 2-methylthio-AMP (2MeSAMP), was added to each blood sample at a concentration to achieve near maximal inhibition. LTA was performed using 10 μM ADP, with and without addition of the additive. The VerifyNow-P2Y12 Assay was also run on these samples. The figure below shows that for all ten blood donors, the percent inhibition (% decrease in aggregation) is less for aggregometry with ADP only (73% avg inhibition) than for aggregometry with ADP and the additive (95% avg inhibition). In addition, agreement between VerifyNow-P2Y12 and LTA using the additive was very good (93% vs 95% avg inhibition). This study demonstrates the benefit of using the additive to achieve P2Y12 specificity.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 5 - 2005

Ms. Barbara E. Stevens
Regulatory and Clinical Affairs
Accumetrics
3985 Sorrento Valley Boulevard
San Diego, California 92121

Re: k051231
Trade/Device Name: VerifyNow™-P2Y12 Assay
Regulation Number: 21 CFR § 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: II
Product Code: JOZ
Dated: May 12, 2005
Received: May 13, 2005

Dear Ms. Stevens:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K051231

Device Name: VerifyNow™-P2Y12 Assay

Indications For Use:

The VerifyNow-P2Y12 Assay is a whole blood assay used in the laboratory or point of care setting to measure the level of platelet P2Y12 receptor blockade.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

A. C. Reeves for L. Bautista
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051231