OCT 6 - 2004 K042423

**510(k) Summary**

**Accumetrics VerifyNow-Aspirin Assay**
**(Formerly Ultegra RPFA-ASA)**

Accumetrics
3985 Sorrento Valley Blvd.
San Diego, CA 92121

September 3, 2004

For information regarding this 510(k) Summary, please contact Accumetrics, Barbara Stevens (858) 643-1600.

Device Names:

| | |
|---|---|
| Trade Name: | VerifyNow-Aspirin Assay |
| Common Name: | VerifyNow-Aspirin Assay |
| Comprised of: | VerifyNow-Aspirin Assay Devices |
| | VerifyNow Wet Quality Controls, Levels 1 and 2 |
| | VerifyNow Instrument |

Classification Name: System, Automated Platelet Aggregation

The Accumetrics VerifyNow System and VerifyNow-Aspirin Assay have been found to be substantially equivalent to previously cleared, automated platelet aggregation devices, specifically to CHRONO-LOG Corporation's Whole Blood Aggregometer (k830749).

Device Description:
The VerifyNow 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 quality control, an assay device internal control, and two levels of external, wet quality control controls. 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, platelet agonist, a peptide, bovine serum albumin, buffer, and stabilizer. 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*-Aspirin assay device to bind activated platelet GP IIb/IIIa receptors. When the activated platelets are exposed to the fibrinogen-coated microparticles, aggregation occurs in proportion to the number of activated platelet receptors. To ensure consistent and uniform activation of the platelets, the agonist arachidonic acid is incorporated into the assay device. The Verify*Now*-Aspirin Assay reports results in Aspirin Reaction Units (ARU).

Intended Use:
The Verify*Now*-Aspirin Assay is a qualitative assay to aid in the detection of platelet dysfunction due to aspirin ingestion in citrated whole blood for the point of care or laboratory setting.

This assay 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 (may be used in patients treated with selective COX-2 inhibitors, e.g., celecoxib (Celebrex®) and rofecoxib (Vioxx®).

This intended use statement is more specific than the broader statement in the labeling for the CHRONO-LOG Whole Blood Aggregometer: "...measuring platelet aggregation in whole blood or platelet-rich plasma." The narrower indication of the Verify*Now*-Aspirin Assay does not raise issues of safety or effectiveness since the aggregometer labeling includes platelet aggregation data for samples post-aspirin ingestion.

Technological Characteristics:
The Verify*Now*-Aspirin 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*-Aspirin Assay is similar to the CHRONO-LOG Whole Blood Aggregometer in that it uses citrated, whole blood samples and measures platelet aggregation. The platelet agonist for the VerifyNow-Aspirin Assay is arachidonic acid, which is also an agonist used with the optical and whole blood aggregometers. The Verify*Now*-Aspirin Assay adds the use of fibrinogen-coated microparticles, which are not used in the CHRONO-LOG aggregometry methods. This difference raises no new issues of safety or effectiveness, as shown by the performance characteristics of the two devices.

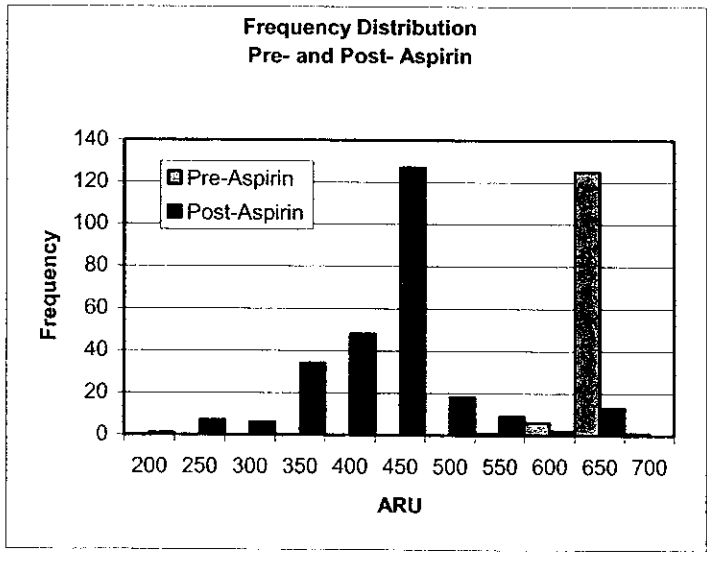
Performance Characteristics:
The VerifyNow-Aspirin Assay performance was evaluated in a multi-center clinical trial on venous whole blood samples from subjects with a history of vascular disease or existence of at least two of eight risk factors for developing vascular disease.

Two aspirin ingestion schemes were studied. Seventy-one of the study's 136 subjects were tested before and after ingestion of 325 mg of aspirin. The remaining 65 subjects were on chronic aspirin therapy of 81 mg per day and were tested at a single post-aspirin time point. Samples were tested with the Verify*Now*-Aspirin Assay and results were compared to the patient's aspirin status. Verify*Now*-Aspirin Assay results were reported as positive or negative, based on a designated cutoff of 550 ARU. The VerifyNow-Aspirin Assay was evaluated against the presence and absence of aspirin ingestion. The concordance table below illustrates performance results.

| Test Result | Aspirin State | |
|---|---|---|
| | Present | Absent |
| Positive (<550 ARU) | 245 | 0 |
| Negative (≥ 550 ARU) | 23 | 141 |

Aspirin Present:
Sensitivity = 91.4%
Specificity = 100%

A reference range of expected values was identified from all patients enrolled in the clinical study. Results are illustrated in a non-parametric frequency distribution below. Values are distributed as pre-aspirin and post-aspirin. The reference range for pre-aspirin samples is 620-672 ARU (2.5 to 97.5 percentile).




Please see package insert for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 6 - 2004

Ms. Barbara Stevens
Regulatory and Clinical Affairs
Accumetrics, Inc.
3985 Sorrento Valley Blvd
San Diego, CA 92121

Re: k042423
Trade/Device Name: Verify*Now*™- Aspirin Assay (Modification to *Ultegra*® RPFA-ASA Assay)
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: Class II
Product Code: JOZ
Dated: September 3, 2004
Received: September 7, 2004

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

# Indications for Use

510(k) Number (if known): K042423

Device Name: VerifyNow™-Aspirin Assay (Modification to *Ultegra*® RPFA-ASA Assay)

Indications For Use:

The VerifyNow Aspirin Assay is a qualitative assay to aid in the detection of platelet dysfunction due to aspirin ingestion in citrated whole blood for the point of care or laboratory setting.

This assay 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 (may be used in patients treated with selective COX-2 inhibitors, e.g., celecoxib (Celebrex®) and rofecoxib (Vioxx®).

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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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