JUN 12 2002

K012701

510(k) Summary

Accumetrics *Ultegra*® System Rapid Platelet Function Assay -ASA (RPFA-ASA)

Accumetrics
3985 Sorrento Valley Blvd.
San Diego, CA 92121

June 6, 2002

For information regarding this 510(k) Summary, please contact Rhonda Moe at Accumetrics, (858) 643-1600.

Device Names:

Trade Name:	*Ultegra* System Analyzer, *Ultegra* System Rapid Platelet Function Assay-ASA (RPFA-ASA) Test Cartridges, RPFA Level One QC and RPFA Level Two QC
Common Name:	*Ultegra* Analyzer, *Ultegra* RPFA-ASA Test Cartridges, RPFA Level One QC and RPFA Level Two QC

Classification Name: System, Automated Platelet Aggregation

The Accumetrics *Ultegra* System Analyzer and RPFA-ASA 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 *Ultegra* 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 analyzer and disposable test cartridge with reagents based on microbead agglutination technology. The quality control system includes an electronic control and two levels of liquid control. The analyzer 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 test cartridge contains a lyophilized preparation of human fibrinogen coated beads, platelet agonist, buffer, and preservative. The patient sample is citrated whole blood, which is automatically dispensed from the blood collection tube into the test cartridge by the analyzer, with no blood handling required by the user. Fibrinogen-coated microparticles are used in the *Ultegra* RPFA-ASA cartridge to bind to available platelet receptors. When the activated platelets are exposed to the fibrinogen-coated microparticles, agglutination occurs in proportion to the number of available platelet receptors. To ensure consistent and uniform activation of the platelets, cationic propyl gallate (c-PG) is incorporated into the assay cartridge to induce platelet

activation without fibrin formation. The *Ultegra* Analyzer is designed to measure this agglutination as an increase in light transmittance. *Ultegra* RPFA-ASA Assay results are reported as Aspirin Reaction Units (ARU).

Intended Use:

The *Ultegra* Rapid Platelet Function Assay-ASA (RPFA-ASA) is a qualitative test to aid in the detection of platelet dysfunction due to aspirin (ASA) ingestion in citrated whole blood for the point of care or laboratory setting.

Not for use in patients with underlying congenital platelet abnormalities, patients with non-ASA induced acquired platelet abnormalities or in patients receiving non-ASA 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 *Ultegra* RPFA-ASA Assay does not raise issues of safety or effectiveness since the CHRONO-LOG aggregometer contains data in its labeling regarding results after aspirin ingestion.

Technological Characteristics:

The *Ultegra* Analyzer and the CHRONO-LOG aggregometer utilize optical detection as the measurement method. Both systems are based on measurement of aggregation/agglutination. Both systems are used to determine platelet function.

Certain new characteristics of the *Ultegra* RPFA-ASA differ from the CHRONO-LOG. Fibrinogen coated microbeads are used in the *Ultegra* RPFA-ASA Assay, but not the CHRONO-LOG aggregometer. The *Ultegra* RPFA-ASA Assay uses the agonist cationic propyl gallate, whereas the CHRONO-LOG uses several different agonists. The *Ultegra* RPFA-ASA Assay includes two levels of liquid control, and the CHRONO-LOG does not.

These differences raise no new issues of safety or effectiveness, as shown by the performance characteristics of the two devices.

Performance Characteristics:

The *Ultegra* RPFA-ASA performance was evaluated in a multi-center clinical trial on venous whole blood samples from subjects with history of vascular disease or existence of at least two of eight risk factors for developing vascular disease.

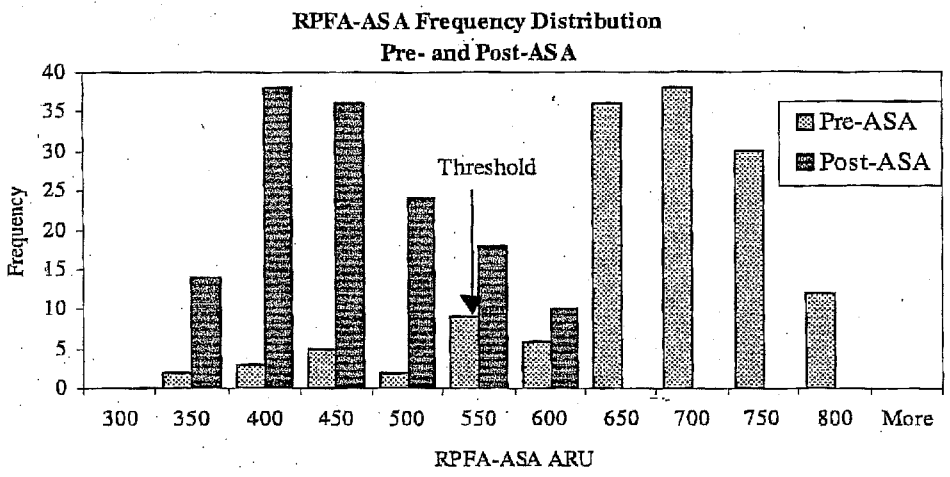
The multi-center clinical trial was designed to study results from patients before and after aspirin ingestion (325 mg). Samples were obtained at four clinical sites from 148 patients at two time points: 1) Pre-ASA, prior to aspirin ingestion and 2) Post-ASA, 2 to 30 hours after ingestion of aspirin. Samples were tested in duplicate with the *Ultegra* RPFA-ASA Assay and compared to the patient's aspirin status. RPFA-ASA results were based on a designated cutoff of 550 ARU (extent of platelet aggregation measured).

Testing was performed on patients newly introduced to aspirin. *Ultegra* RPFA-ASA was evaluated against the presence and absence of aspirin ingestion. The concordance table below illustrates performance results.

TEST RESULT	ASA STATE	
	PRESENT (n=143)	ABSENT (n=140)
POSITIVE (< 550 ARU)	129	21
NEGATIVE (≥ 550 ARU)	11	122

ASA Present:
Sensitivity = 92.1% (86.4% to 96.0%)
Specificity = 85.3% (78.4% to 90.7%)

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 no aspirin ingestion (pre-ASA) and 2 to 30 hours after ingestion of 325 mg aspirin (post-ASA). The reference range for pre-ASA samples is 399-780 ARU (based on a 2.5 to 97.5 percentile).



Please see package insert for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 12 2002

Ms. Rhonda Moe
Director, Regulatory and Clinical Affairs
Accumetrics, Inc.
3985 Sorrento Valley Boulevard
San Diego, California 92121

Re: k012701
Trade/Device Name: *Ultegra*® System Rapid Platelet Function Assay – ASA (RPFA-ASA)
Regulation Number: 21 CFR § 864.5700
Regulation Name: System, Automated Platelet Aggregation
Regulatory Class: II
Product Code: JOZ
Dated: March 13, 2002
Received: March 14, 2002

Dear Ms. Moe:

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 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); 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.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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): K012701

Device Name: *Ultegra*® System Rapid Platelet Function Assay-ASA (RPFA-ASA)

Indications For Use:

The *Ultegra*® Rapid Platelet Function Assay-ASA (RPFA-ASA) is a whole blood assay used to measure platelet response to aspirin.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012701

510(k) Number (if known): K012701

Device Name: *Ultegra* Rapid Platelet Function Assay-ASA (RPFA-ASA)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012701