NOV 17 1997

510(k) Summary of Safety and Effectiveness Information

Dade® PFA-100™ Platelet Function Analyzer
Dade® PFA Collagen/Epinephrine Test Cartridge
Dade® PFA Collagen/ADP Test Cartridge
Dade® PFA Trigger Solution
February 7, 1997

Dade International, Inc.
2173 NW 99th Avenue
Miami, FL 33172
Contact Person: Bryan Schneider at 305-592-2311 extension 5769, or by facsimile at 305-392-5622

Trade or Proprietary Name: Dade® PFA-100™ Platelet Function Analyzer
Dade® PFA Collagen/Epinephrine Test Cartridge
Dade® PFA Collagen/ADP Test Cartridge
Dade® PFA Trigger Solution

Common or Usual Name: PFA-100 system

Classification Name: None

Registration Number:

Manufacturing Sites (Reagents)

Dade International, Inc.
1851 Delaware Parkway
Miami, FL 33125 — 1017272

Dade International, Inc.
2173 99th Ave.
Miami, FL 33172 — 1025506

Manufacturing Site (Instrument)

Dade International, Inc.
Microscan Division
2040 Enterprise Blvd.
West Sacramento, CA 95691 — 2919016

The Dade®PFA-100™ system is substantially equivalent in intended use to the Chrono-log Aggregometer, manufactured by Chrono-log Corporation, Haverton, PA, that was previously cleared under Document Control Nos. K771198, K830749 and K851025. The associated Chrono-log aggregation reagents were most recently cleared under Document Control No. K922800.

The Dade® PFA-100™ system is an instrument and test reagents in which the process of platelet adhesion and aggregation following a vascular injury is simulated *in vitro*. Platelet

dysfunction detected by the PFA-100 system may be acquired, inherited or induced by platelet inhibiting agents.

The PFA-100 system allows for rapid evaluation of platelet function on small samples of anticoagulated whole blood. The single use test cartridge reagents consists of a number of integrated parts including a capillary, a sample reservoir and a biologically active membrane with a central aperture. By application of a constant vacuum, anticoagulated whole blood is aspirated from the sample reservoir through the capillary and the aperture under standardized rheological conditions that expose platelets to high shear stress. The membrane is coated with collagen and one additional agonist. At the beginning of a test, Trigger Solution is dispensed to wet the membrane. Similar to the *in vivo* mechanism, platelets adhere and aggregate at the aperture thereby gradually diminishing and finally arresting the blood flow. The instrument determines the time from the start of the test until the platelet plug occludes the aperture, and reports that time interval as the Closure Time. Platelet plug formation in the PFA-100 system is dependent on adequate platelet activity and adequate von Willebrand factor status. Therefore, the Closure Time is an indicator of the platelet function in the analyzed whole blood sample.

Data to support substantial equivalence to the predicate device was generated in a clinical study. The clinical study was designed to demonstrate the substantial equivalence between the PFA-100 (proposed device) and the Chrono-log Aggregometer (predicate device) by comparing the clinical specificity and clinical sensitivity between the systems. A total of 328 specimens were tested with the proposed and the predicate devices. This population, which represented 63% females and 37% males, consisted of 176 samples from subjects with normal platelet function and 152 samples with platelet dysfunction. The group of platelet dysfunction samples were obtained from subjects with von Willebrand disease, aspirin-induced dysfunction, and Glanzmann's thrombasthenia. The Platelet Function Status of each sample was based upon results from a platelet function test panel and clinical history.

Clinical sensitivity and specificity of the proposed and predicate device were calculated against the Platelet Function Status. The Clinical Sensitivity and Specificity of the proposed device are statistically comparable to the calculated clinical sensitivity and specificity for the predicate device. The overall agreement by direct comparison of clinical categorization between the proposed and predicate devices was calculated at 90.1%.

	Proposed Device PFA-100	Predicate Device Chrono-log Aggregometer
Clinical Sensitivity	96.1%	97.4%
Clinical Specificity	88.6%	91.5%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 1997

Mr. Bryan Schneider
Senior Regulatory Specialist
Regulatory Affairs
Dade International Inc.
P.O. Box 520672
Miami, FL 33152-0672

Re: K970505/S2
Dade PFA-100 Platelet Function Analyzer
Regulatory Class: II
Product Code: JOZ
Dated: August 25, 1997
Received: August 26, 1997

Dear Mr. Schneider:

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 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 (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): K970505

Device Name: Dade PFA-100 Platelet Function Analyzer

Indications For Use:

To aid in the detection of platelet dysfunction in citrated human whole blood for use in patients with a suspected disorder of primary hemostasis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K970505

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)