MAY 14 1999

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Center for Devices and Radiological Health
Office of Device Evaluation
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850
January, 1999

510(k) Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

The assigned 510(k) number is K990566.

Submitted by: Greg Godlevski
Director of Software Development

Address: Cardiovascular Diagnostics, Inc.
5301 Departure Drive
Raleigh, NC 27616

Phone: 1-800-247-4234

Fax: 1-919-954-9932

Contact: Greg Godlevski
Director of Software Development

or

Peter Scott
VP of Quality Assurance and Regulatory Affairs

Date of Summary: January, 1999

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Trade name: Thrombolytic Assessment System (TAS)

Common Name: TAS Analyzer with software version 4.0

Classification Name: systems for in vitro coagulation studies, automated or semiautomated instruments and associated reagents and controls used to perform a series of coagulation studies and coagulation factor assays (Class II. 21 CFR864.5425)

Predicate Device: The proposed TAS Analyzer with software version 4.0 is substantially equivalent to the previously cleared TAS Analyzer with software version 2.03. The 510(k) number for the original submission is K933092/A1.

Description of the Device: This 510(k) notification is being submitted for the purpose of providing data proving that the current software version 4.0 is substantially equivalent to the 510(k) cleared software version 2.03 and, that while there have been changes to the software, there are no new issues raised regarding safety or effectiveness. The TAS Analyzer with software version 4.0 provides a method of testing for coagulation parameters in samples of citrated or non-citrated blood or citrated plasma. The instrument is designed to be used with disposable test cards. The test cards are approximately the size of a credit card with a magnetic stripe on the back which is encoded with data including the test type and lot specific test parameters. The cards contain dried reagent which includes paramagnetic iron oxide particles in a small thin reaction chamber. When a sample is added to the test card, the reagent, particles, and sample mix. The instrument has a permanent magnet and an electromagnet which move the particles in the sample. The particle motion is monitored with a light source and detector. The electromagnet is energized repeatedly for half a second then turned off for half a second. When the electromagnet is on, the particles align themselves with the magnetic field lines produced by the electromagnet. When the electromagnet is off, the particles align with the weaker field lines of the permanent magnet. As the sample clots, the motion of the particles is restrained. Software algorithms monitor the change in particle motion and determine features such as clotting time, lysis time, or other mathematically derived characteristics. These values are then reported to the user.

The software provides additional features to the operator such as optional operator identification codes, storage of 1000 test results, and a QC lockout mode which helps

ensure that controls are performed. Most features are available to the user in one of two ways. Features which are intended for any operator to access are listed as options on the User menu. Features which are limited to supervisors are listed as options on the Supervisor menu. Access to the Supervisor menu is limited by a password.

This new software version adds new features such as Electronic Quality Control and improves some existing features. Many of the changes are minor modifications to the user interface. Other changes are more significant, providing the user with four new test types and a few new options.

A 510(k) will be filed for each of the new tests individually. In each case, the addition to the software of the capability to process the test does not allow the operator to perform the test without having the new test cards. The test cards for each of these tests will not be sold for human diagnostic or prognostic purposes until clearance has be granted by the FDA. This 510(k), which is for the new software version, does not address the clinical performance or efficacy of these new test cards.

The 4.0 software version has been developed under design control with the features verified and the design validated. The design, verification, and validation of the new and modified operator features in the 4.0 software version are covered in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Greg Godlevski
Director of Software Development
Cardiovascular Diagnostics, Inc.
5301 Departure Drive
Raleigh, North Carolina 27616

Re: K990566
Trade Name: TAS™ Analyzer with Software Version 4.0
Regulatory Class: II
Product Code: JPA
Dated: February 22, 1999
Received: February 22, 1999

Dear Mr. Godlevski:

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 (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

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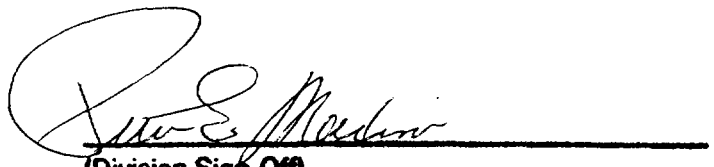
Intended Use

The TAS analyzer with software version 4.0 is intended to be used with TAS test cards to monitor the hemostatic activity of whole blood and plasma samples. The TAS analyzer is a portable system designed to be used in non-laboratory testing environments by healthcare professionals. TAS test results are reported in quantitative units of measurement.



(Division Sign-Off)
Division of **Clinical Laboratory Devices**
510(k) Number K990566