

15981206

MAY 26 1998

510(k) Summary of Safety and Effectiveness Information

Submitted by: Greg Godlevski
Director of Software Development

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or

Peter Scott
VP of Quality Assurance and Regulatory Affairs

Date of Summary: March, 1998

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Trade Name: TAS Result Acquisition System (TRAQS)

Common Name: TRAQS

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

Description of Accessory: TRAQS is a software package designed for computers running the Windows 95 operating system. TRAQS provides features which allow the user to collect, view, and sort patient and control results from Thrombolytic Assessment System (TAS) analyzers. TRAQS also provides a method for the user to enter normal ranges and then compare the stored data set against the ranges. Stored results which fall outside the appropriate range are flagged on the screen and in printouts as out of range. Sets of stored TAS results displayed on the screen can be saved to archive files for later viewing or printing. TRAQS also keeps track of the number of results collected from TAS analyzers and can display this data by TAS serial numbers. No capability is provided to alter the data associated with TAS results. A comprehensive users manual is supplied with the software.

Intended Use: TRAQS software was designed specifically to gather and archive results from TAS analyzers. TRAQS is also intended to indicate whether collected results are within user defined ranges.

Development Environment: The TRAQS application was developed under the control of the CVDI Software Development Life Cycle (SDLC). The CVDI SDLC is based on IEEE software engineering standards. The CVDI SDLC requires that, before any software is written for a product, a Concept document, a Systems Requirements document, and a Functional Specification document are written. These documents have been developed for the TRAQS application. The Functional Specification is of particular importance, since it is used to create the test scripts needed during the Validation phase of a project. Prior to the TRAQS Construction phase, the TRAQS Test Plan was written which described the testing methods and pass/fail criteria which would be employed during the Validation phase.

The SDLC dictates that traceability is to be maintained from the System Requirements through Validation. This is accomplished for the TRAQS application with Traceability Matrices that relate the System Requirements to the Functional Specifications and the Functional Specifications to the individual Functional Test Scripts therefore ensuring full coverage of all application features.

Configuration management topics are covered in a specific TRAQS Configuration Management document which describes the creation of software libraries, software module naming conventions, change control, interface control, and status accounting.

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Test Plan Summary and Release Criteria: The TRAQS Test Plan states the Validation phase of the TRAQS software development effort shall consist of Functional testing of the TRAQS software. Functional testing consists of the generation of test scripts which specifically test each of the requirements identified in the TRAQS Functional Specification. The Test Plan states that a Functional Test Protocol is to be written to guide the creation and execution of the test scripts.

The Pass/Fail criteria for the Validation phase is stated in the TRAQS Test Plan. The Pass/Fail criteria requires that all test scripts are completed successfully by the version of software under test.

Test Data Summary: Two types of test data sets were used during the Functional testing of the TRAQS software.

The first type of data set consisted of modified TRAQS database files. Since the TRAQS software uses a Microsoft Access database engine, the Microsoft Access application could be used to create TRAQS databases with known record sets. These known record sets were used to methodically test TRAQS features such as viewing, sorting, and archiving records.

The second type of data set consisted of TAS records received from a TAS analyzer running with modified software. The modification to the TAS analyzer created a function which filled the TAS analyzer's memory with a special set of test records. The set of test records represented every possible combination of test type, sample type, error condition, patient id, length, etc. This record set was then transferred to the TRAQS software using the normal operating procedure for capturing TAS results. TRAQS features such as viewing, sorting, printing, and archiving were then tested to ensure that TRAQS would properly handle all combinations of data that could be received from a TAS analyzer. Additionally, a subset of this record set was designed to specifically test the software's ability to properly handle year 2000 issues.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 26 1998

Peter J. Scott
Vice President of Quality Assurance
and Regulatory Affairs
Cardiovascular Diagnostics Inc.
5301 Departure Drive
Raleigh, NC 27616

Re: K981206
Trade Name: Tas Results Data Acquisition System (TRAQS)
Regulatory Class: II
Product Code: GKP
Dated: March 27, 1998
Received: April 1, 1998

Dear Mr. Scott:

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 requirement, 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.

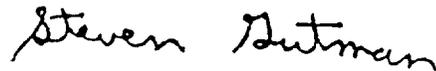
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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): _____

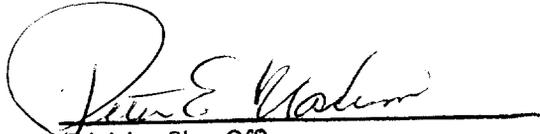
Device Name: Tas Results Data Acquisition System (TRAQS)

Indications For Use:

The TRAQS is a database management system that is designed specifically to collect, organize, and store Thrombolytic Assessment System (TAS) analyzer records

(PLEASE DO NOT WRITE 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 _____

Prescription Use
(Per CFR 801.109)

OR

Over-The-Counter use _____
(Optional Format 1-2-96)