

FEB 1 2000

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K993553

Name: FVIII Inhibitor

Equivalence: PF4 ELISA

Description: FVIII Inhibitor Assay is an ELISA platform which is designed to detect IgG antibodies to human recombinant FVIII in human plasma samples. Recombinant human FVIII molecules are passively immobilized in microtiter wells. Patient plasma is tested against wells containing immobilized recombinant FVIII and compared to the reaction obtained from the negative control sera included in the kit. The results are obtained in optical density (OD) values. The patient samples having OD values greater than the cutoff value are regarded as being positive.

Intended Use: FVIII Inhibitor Assay is a solid phase Enzyme-Linked Immunosorbent Assay (ELISA) which is used to detect IgG antibodies reactive with recombinant human FVIII.

Comparison of FVIII Inhibitor Assay to the predicate device:

The following table demonstrates the comparison:

Feature/ Characteristic	GTI-PF4 ELISA	GTI-FVIII Inhibitor Assay
INTENDED USE	Solid Phase ELISA for the detection of heparin-associated antibodies reactive with PF4/PVS complexes.	Solid Phase ELISA for the detection of antibodies directed against epitopes on recombinant human factor VIII molecule
IMMUNOASSAY FORMAT	SOLID PHASE ELISA	
TYPE OF TEST	QUALITATIVE	

ANTIGEN SOURCE	Affinity purified Human PF4	Recombinant human FVIII
TARGET ANTIGEN IMMOBILIZATION	PF4/PVS complex passively adsorbed in microtiter wells	Recombinant human FVIII Passively adsorbed in microtiter wells
INTERPRETATION OF TEST RESULTS	The OD for each microtiter Well is compared to a cut off value in order to determine the positive & negative results	The OD for each microtiter well is compared to a cutoff value in order to determine the positive & negative results
TYPE OF ANTIBODIES DETECTED	Heparin-associated antibodies Reactive with PF4/PVS complexes	FVIII inhibitor antibodies reactive with recombinant human factor VIII

Support of 510(k) with Clinical Data

GTI-FVIII Inhibitor Assay was compared to Bethesda assay in two independent clinical laboratories. Results indicated that GTI-FVIII Inhibitor Assay detects FVIII antibodies with a concordance of 89.6%, sensitivity of 98.9%, and negative predictive value of 98.8% as compared to Bethesda assay.

Support of 510(k) with Non-Clinical Data

Lot-to-lot testing of GTI-FVIII Inhibitor Assay was comparable between three different lots.

Tech-to-tech testing of GTI-FVIII Inhibitor Assay showed good correlation of the results obtained by three different individuals.

Stability data carried out over a 27 month period indicated that GTI- FVIII Inhibitor Assay remains stable during the dating period.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 2000

Mr. Michael Moghaddam
Director, Product Development
Genetic Testing Institute
150 North Patrick Boulevard
Brookfield, Wisconsin 53045-5837

Re: K993553
Trade Name: GTI-FVIII Inhibitor Assay
Regulatory Class: II
Product Code: GGP
Dated: January 4, 2000
Received: January 5, 2000

Dear Mr. Moghaddam:

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 (Pre-market 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.

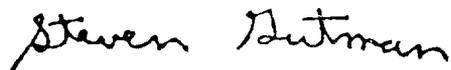
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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): K993553

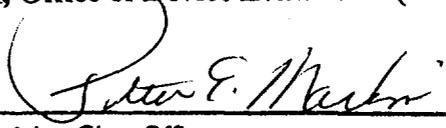
Device Name: _____

INDICATIONS FOR USE

GTI-FVIII Inhibitor Assay is designed as a solid phase Enzyme-Linked Immunosorbent Assay (ELISA). The product is intended to be used as an *in vitro* diagnostic kit by hemostasis and other laboratories providing factor VIII inhibitor assay to assist in screening samples for the presence of alloantibodies to epitopes on FVIII molecule.

(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 K993553

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)