

OCT 22 1998

# Ramco Laboratories Inc.

4507 Mt. Vernon • Houston, Texas 77006 • (713) 526-9677 • Toll Free Number 1-800-231-6238 24 hrs.  
Fax No.: 713-526-1528

## 510(k) SUMMARY

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

The assigned Premarket Notification [510(k)] Number is: K983107

**Submitter:** Ramco Laboratories, Inc.  
4507 Mt. Vernon  
Houston, Texas 77006

**Phone #:** (713) 526-9677  
**Fax #:** (713) 526-1528

**Contact Person:** Jeffrey B. Grubb, President

**Dated Prepared:** September 3, 1998

**Device Name:** von Willebrand Factor Antigen Assay

**Trade Name:** *VFE*

**Common Name:** Enzyme Assay for von Willebrand Factor

**Classification Name:** Enzyme Linked Immunoassay

**Predicate Device Name:** SPECTRO vWF  
Ramco Laboratories, Inc.  
4507 Mt. Vernon  
Houston, Texas 77006  
510(k) #K861159

Description of Device:

*VFE* is an enzyme immunoassay, in microplate format, intended for the *in vitro* quantification of von Willebrand Factor antigen in serum or plasma as an aid to differentiate patients with von Willebrand disease from those with classical Hemophilia A.

This assay represents an updated technical format, with performance improvements, when compared to the predicate device.

Intended Use and Indications for Use:

*VFE* is intended for use as an aid in the diagnosis and management of patients having an increased tendency to bleed. It is useful to differentiate patients with von Willebrand disease from those with Classical Hemophilia A (Factor VIII coagulant deficiency). The later group of patients have prolonged activated partial thromboplastin time (PTT) but have normal or increased concentrations of von Willebrand Factor (vWF) in their plasma. In contrast, patients with von Willebrand disease have depressed levels of vWF.

*VFE* should be used whenever a patient demonstrates:

- i) a decrease in procoagulant activity as measured by activated PTT; and/or
- ii) a prolonged bleeding time.

Summary of Technological Characteristics of Predicate and Proposed Device

	<u>VFE</u>	<u>SPECTRO vWF</u>
Methodology	Sandwich ELISA	Sandwich ELISA
Solid phase	coated microtiter wells	coated beads
Material	polystyrene	polystyrene
Antibody	rabbit anti-human vWF, IgG from (NH4)2SO4	rabbit anti-human vWF, IgG from (NH4)2SO4
Conjugate	HRP labeled anti-human vWF antibody Labeled anti-human vWF	Alkaline phosphatase
Antibody	sheep	rabbit

Sample Material	serum, plasma in EDTA or citrate	plasma in EDTA or citrate
Sample dilution	1:51 and 1:102 if Needed	1:51
Sample volume	20 microliters 10 microliters if needed	50 microliters;
Incubations	2	2
Length #1	2 hours, 10 min.	2 hours
Length #2	30 minutes	30 minutes
Washes	4	as needed
Wash material	1X diluted wash Buffer	deionized water
Calibrator	Lyophilized, pre-diluted human plasma pool	liquid purified human vWF in buffer
Number	5 dilutions per assay	one per assay
Assay Reading	microplate reader	spectrophotometer
Wavelength	450 nm	492 nm
Background correction	yes	no
Substrate	TMB	phenylphosphate disodium,4-amino-tipyrine
Components/kit	1	2
Color developer	none	potassium ferricyanide
Stop Solution	1% HCl	none

Non-clinical Performance Discussion:

The following non-clinical performance data comparison indicates that SPECTRO vWF, the predicate test, and *VFE* have similar characteristics and are substantially equivalent.

<u>Parameter</u>	<u><i>VFE</i></u>	<u>SPECTRO vWF</u>
Sensitivity	0.78% N	0.23% N
Intra-assay reproducibility - CV	5.0 - 5.8	6.2 - 8.0
Inter-assay reproducibility - CV	7.0 - 11.5	6.3 - 12.8
Accuracy - R	0.849* (n = 118)	0.96** (n = 24)

\*compared to predicate test results

\*\*original comparison versus Laurell Rocket electrophoresis results

Conclusions from Non-clinical Testing:

Based on the above results the performance characteristics of, *VFE*, the subject device, and SPECTRO vWF, are substantially equivalent. Since these two tests have very similar technological characteristics, this conclusion is not unexpected.



OCT 22 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Jeffrey B. Grubb  
President  
Ramco Laboratories, Inc.  
4507 Mt. Vernon  
Houston, Texas 77006

Re: K983107  
Trade Name: VFE  
Regulatory Class: II  
Product Code: GGP  
Dated: September 3, 1998  
Received: September 4, 1998

Dear Mr. Grubb:

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.

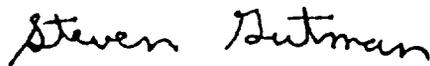
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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" (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 I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### INDICATIONS FOR USE STATEMENT

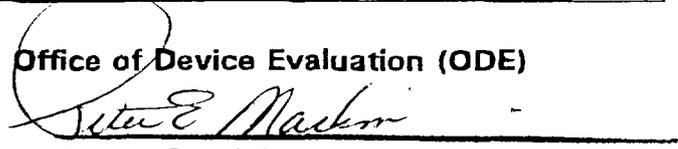
510(k) Number: K983107

Device Name: VFE

Indications for Use: The *VFE* assay is an *in vitro* enzyme immunoassay for quantifying the concentration of von Willebrand Factor Antigen in human plasma to aid in differentiating patients with von Willebrand disease from those with Classical Hemophilia A.

(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 K983107

Prescription Use

OR

Over-The-Counter