K973823

NOV 13 1997

510(k) Summary

1. Submitter's Name/Contact Person

Joseph M. Califano Manager, Regulatory Affairs

Address

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Date Prepared

26 September 1997

2. Device Name

Trade Name: VIRGO ® cANCA Kit (EIA method)
Common Name: PR3 Antibody Kit
Classification Name: Antineutrophil Cytoplasmic Antibodies test system

3. Predicate Device

Scimedx EIA Kit For the Detection of Anti-PR3 Antibodies
{510 (k) Docket No. K 954105}

3. Description of Device

An enzyme-linked immunosorbent assay (ELISA) designed for the detection and measurement of autoantibodies to the antigen Proteinase 3 in human serum.

The ELISA methodology is commonly used for serum antibody evaluations. Purified PR3 antigen has been attached to the inner surfaces of the microwell plate. During the initial incubation step, antibodies in patient serum bind specifically to the immobilized antigen and remain in place after a wash step.

A second antibody which is conjugated to horseradish peroxidase (HRP) is used to recognize the "heavy + light" chain regions of the patient's antibodies remaining after the wash step. In the wells where the second antibody remains bound, the conjugated HRP catalyzes a color change in the substrate, tetramethyl benzidine (TMB). After the reaction is stopped, the color is read in an EIA Plate reader.

4. Intended Use of Device

An enzyme-linked immunosorbent assay (ELISA) designed for the detection and measurement of autoantibodies to the antigen Proteinase 3 in human serum. The test is intended as an aid in the diagnosis of current or past autoimmune mediated vasculitides.

5.(A) Technological Characteristics

Proposed Device

The **VIRGO ® cANCA Kit** is an enzyme-linked immunosorbent assay. The device utilizes optical density as a measure of antibody presence, with an established cutoff between a positive and a negative reaction.

Predicate Device

The **Scimedx ANTI-PR3 ANTIBODY EIA** is also an enzyme-linked immunosorbent assay. The device utilizes optical density as a measure of antibody presence, with an established cutoff between a positive and a negative reaction.

5.(B) Performance Data

Precision

To evaluate precision, both inter-assay and intra-assay studies were conducted. The results are summarized below:

Eight serum samples were assayed in duplicate twice a day for five different days.

Sample	Mean OD	Std. Dev.	% CV	Mean Units	Std. Dev	% CV
1	1.444	0.112	7.8	7.3	0.6	7.9
2	1.060	0.070	6.6	5.3	0.4	8.0
3	0.128	0.020	N/A	0.6	0.1	N/A
4	0.037	0.009	N/A	0.2	0.04	N/A
5	0.770	0.075	9.7	3.7	0.5	12.3
6	0.586	0.059	10.1	3.0	0.3	11.1
7	0.515	0.039	7.5	2.6	0.2	8.2
8	0.351	0.040	11.5	1.8	0.2	11.7

The assay controls {Positive, Negative, and Cutoff Serum} were assayed concurrently twice a day for each of the five days.

Sample	Mean OD	Std. Dev.	% CV
Negative Control	**0.011**	**0.004**	**N/A**
Positive Control	0.863	0.068	7.8
Cutoff Serum	0.197	0.012	6.2

B. Intra-assay

Eight serum samples were assayed 20 consecutive times in a single run.

Sample	Mean OD	Std. Dev.	% CV	Mean Units	Std. Dev.	% CV
1	1.197	0.073	6.1	6.1	0.4	6.7
2	0.818	0.045	5.6	4.1	0.2	5.7
3	0.131	0.005	3.7	0.7	0.02	3.7
4	0.057	0.003	4.4	0.3	0.01	4.4
5	0.563	0.034	6.1	3.0	0.2	6.4
6	0.460	0.032	6.9	2.4	0.1	6.1
7	0.407	0.020	4.9	2.2	0.1	4.9
8	0.269	0.018	6.8	1.5	0.1	6.7

Comparison Testing

A total of 108 serum specimens {28 from individuals with Wegners Granulomatosis, and 80 from normal apparently healthy donors} were concurrently assayed by both the predicate device and the proposed device. The results are presented in the tables that follow:

Table 1.1 Panel 1, n = 28 { Positive Panel}

	Predicate Device		
	Positive	Negative	Total
Proposed Device			
Positive	28	0	28
Negative	0	0	0
Total	28	0	28

Relative Sensitivity = 100.0 % {28/28}, $_{0.95}$ confidence interval = 87.9 % to 100 %

Table 1.2 Normals, n = 80

	Predicate Device		
	Positive	Negative	Total
Proposed Device			
Positive	0	0	0
Negative	0	80	80
Total	0	80	80

Relative Specificity = 100 % {80/80}, $_{0.95}$ confidence interval = 95.4 % to 100 %

Interfering Substances

Lipemic, icteric, and hemolytic samples were evaluated with the assay following **NCCLS Document EP7-P Proposed Guideline, Interference Testing in Clinical Chemistry**. The results indicate that there is no significant effect (<15 % variation) on the assay for samples with:

Hemoglobin concentration:	≤ 500 mg/dL
Bilirubin concentration:	≤ 20 mg/dL
Lipid concentration:	≤ 3000 mg/dL

Prozone

The **VIRGO ® cANCA Kit** was used to assay several high titered serum samples to determine if the kit would return unexpectedly low values. The results of this evaluation indicate that the kit gives appropriately high positive results with high titered sera.

Conclusions

The results of the comparative studies support the claim that the proposed device is substantially equivalent to the predicate device and performs as an effective screening assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 1997

Mr. Joseph M. Califano
Manager, Regulatory Affairs
Hemagen Diagnostics, Inc.
34-40 Bear Hill Road
Waltham, Massachusetts 02154

Re: K973823
Trade Name: VIRGO® cANCA Kit (EIA method)
Regulatory Class: II Tier: II
Product Code: MOB
Dated: September 30, 1997
Received: October 7, 1997

Dear Mr. Califano:

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.

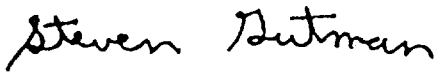
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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,



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

K973823

Device Name: VIRGO ® cANCA Kit

Indication(s) For Use

This enzyme-linked immunosorbent assay (ELISA) is indicated for the detection of autoantibodies to the antigen Proteinase 3 in human serum. The presence of PR-3 antibodies, in combination with clinical observations and other serological tests, can aid in the diagnosis of Wegener's granulomatosis (WG) and other conditions associated with elevated anti-neutrophil cytoplasmic antibodies (ANCA)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maddux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973823

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