

2973819

MAR 10 1998

I.1. 510(k) SUMMARY

Submitter: Terry McGovern
bioMérieux Vitek, Inc.
1022 Hingham St.
Rockland, MA 02370
(617) 871-4442

Date: September , 1997

Device: VIDAS D DIMER (DD Assay)

Classification

Name: 21CFR 864.7320. Fibrinogen and fibrin split products, antigen, antiserum, control (81DAP)

Common or

Usual Name: Enzyme-linked Fluorescent Immunoassay (ELFA), D-Dimer (DD)

Predicate Device: American Bioproducts Asserachrom D-Di Kit (K862156)

Intended Use: The VIDAS D-Dimer (DD) Assay is for the quantitative detection of fibrin degradation products (FbDP) in human plasma. It is intended to aid in the diagnosis of deep venous thrombosis and pulmonary embolism disease.

Device Description:

The VIDAS D-Dimer assay is an enzyme-linked fluorescent immunoassay (ELFA) performed on an automated VIDAS instrument. All assay steps and assay temperature are controlled by the instrument.

A pipette tip-like disposable device known as the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. Reagents for the assay are located in the sealed VIDAS DD Reagent Strips.

The VIDAS D-Dimer kit contains 60 SPRs, 60 Reagent Strips, 2 Bottles of Calibrator, 2 Bottles each level of Positive Control (three levels) and 1 bottle of Diluent. The Kit contains a sufficient number of SPR's and Strips to perform 60 Tests.

The SPR is coated with mouse anti-FbDP antibodies. The Strip contains the reagents necessary to perform the assay, as well as a sample well for placement of the specimen. Each DD test requires one DD Reagent Strip and one DD SPR.

510(k) SUMMARY (CONT.)

SYNOPSIS OF PERFORMANCE TESTING

1. **Correlation:** Comparison of the VIDAS D-Dimer assay with the American Bioproducts Asserachrom DDi kit yields a line with the equation $y = 1.06x - 50.4$ and a correlation coefficient of 0.90.
2. The calibrator in the kit ensures that the master curve stored by the VIDAS instrument is valid for the shelf life of that kit. The body of data supports the use of a single calibrator for this purpose.
3. **Sensitivity (analytical):** The VIDAS D-Dimer assay is designed to measure fibrin degradation products (FbDP) between 45 ng/ml and 1000 ng/ml. The lowest measurable level of FbDP (limit of detection) that can be distinguished from zero with 95 % probability is 45 ng/ml.
4. **Specificity:** The specificity of the two monoclonal antibodies used in the VIDAS D-Dimer assay was demonstrated by testing the antibodies against different concentrations of purified fibrinogen degradation products (X, Y and D) and fibrin degradation products (D-Dimer). Each antibody was tested separately and showed a weak cross reaction with fibrinogen degradation products. Testing the antibodies in combination demonstrated that the antibodies recognized D-Dimer and D-Dimer containing fibrin derivatives. However, they do not cross react with fibrinogen or its degradation products.
5. **Interfering Substances:** No assay interference was demonstrated when testing the VIDAS D-Dimer assay using spiked hemolyzed, icteric or lipemic specimens. Although interference linked to the presence of hemoglobin, bilirubin or lipids has not been observed at the concentrations tested, using hemolyzed, icteric or lipemic samples is not recommended when using the VIDAS D-Dimer assay.
6. **Precision/Reproducibility:**
 - a. Intra-assay precision studies showed coefficients of variation ranging from 3.8 % to 5.8 % over the reportable range of the assay.
 - b. Inter-assay reproducibility over an eight-week time period yields coefficients of variation that do not exceed 7.6 %.
 - c. Inter-assay, inter-instrument reproducibility for four different serum samples in 8 runs on 8 different instruments yields coefficients of variation that do not exceed 4.9 %.

When the VIDAS D-Dimer assay is used as instructed in the package insert, the above statements are true. The package insert should always be consulted along with the Operator's Manual to ensure that the assay is being performed properly. For additional information, references are listed in the package insert.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 10 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Terry McGovern
• Manager, Quality Assurance/Regulatory Affairs
bioMerieux Vitek, Inc.
1022 Hingham Street
Rockland, Massachusetts 02370

Re: K973819
VIDAS D-Dimer (DD) Assay
Regulatory Class: II
Product Code: DAP
Dated: January 15, 1998
Received: January 20, 1998

Dear Mr. McGovern:

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 (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.

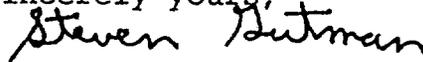
Page 2

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/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

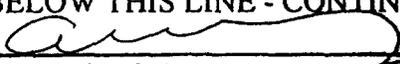
510(k) Number (if known): K 973819

Device Name: VIDAS D-Dimer Assay (DD)

Indications for Use:

The VIDAS D-Dimer (DD) assay is intended for use with a VIDAS (Vitek ImmunoDiagnostic Assay System) instrument as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of fibrin degradation products (FbDP) in plasma (trisodium citrate). The VIDAS D-Dimer assay is intended for use as an aid in the diagnosis of deep venous thrombosis and pulmonary embolism disease.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K 973819

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

or

Over-the-Counter Use