SEP - 2 2003

K030328

## Section J. 510(k) Summary

**Applicant Name and Address**

| | |
|---|---|
| Applicant: | bioMerieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Sandra Perreand |
| Phone Number: | (314) 731-8594 |
| Fax Number: | (314) 731-8689 |
| Date of Preparation: | August 25, 2003 |

**Device Name**

| | |
|---|---|
| Trade Name: | VIDAS D-Dimer New (DD2) Assay |
| Common Name: | Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of fibrin degradation products (FbDP) |
| Classification Name: | Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control |

**Predicate Device**

| | |
|---|---|
| Trade Name: | VIDAS D-Dimer (DD) New Assay, K020810 |

**Device Description**

The VIDAS® D-Dimer New (DD2) Assay is an automated quantitative test for use on the VIDAS instrument (K891385) for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma using the enzyme-linked fluorescent immunoassay (ELFA) technique. The instrument controls all assay steps and assay temperatures. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed DD2 Reagent Strips.

**Intended Use**

The VIDAS® D-Dimer New is an automated quantitative test for use on the VIDAS analyzer for the immunoenzymatic determination of fibrin degradation products (FbDP) in citrated human plasma using the ELFA techniques (Enzyme Linked Fluorescent Assay). The VIDAS® D-Dimer New assay is indicated for use in conjunction with a clinical Pre-test Probability Assessment (PTP) model in excluding deep venous thrombosis (DVT) and Pulmonary Embolism (PE).

**Technological Characteristic Summary**

Summary of Similarities and Differences to Predicate Device

Major Similarities Include:

1) The VIDAS D-Dimer assays are identical except for the proposed modification in the Indications for Use.

Major Differences Include:

1) The major difference between the two VIDAS assays is that we are expanding the indications for use for the assay.

**Performance Data**

Data was taken from a study carried out on 302 patients admitted consecutively to the emergency unit with suspected pulmonary embolism or deep venous thrombosis (frequency of venous thromboembolic disease: 23.7%).

For a cutoff at 500ng/ml, the results of the VIDAS D-Dimer New assay were as follows:

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|---|---|
| Sensitivity: | 100% (95% CI, 95.0-100) |
| Specificity: | 33% (95% CI, 27.0-39.1) |
| Neg. Predictive Value | 100% (95% CI, 95.3-100) |

Frozen samples collected from patients enrolled in a multi-center, prospective cohort study were used to validate the diagnostic utility of VIDAS D-Dimer New to exclude a diagnosis of deep vein thrombosis (DVT). Consecutive eligible outpatients (n = 556) with a first suspected DVT episode were evaluated at three hospitals during the course of the study. Using the previously validated, standardized clinical Wells model to estimate the probability of DVT, patients were classified as having a high, moderate, or low pretest probability (PTP) of DVT.

The VIDAS D-Dimer New assay was performed without knowledge of the PTP assessment results and the clinical outcome of the patients from which the samples were derived. A clinical cut off value of 500 ng FEU/ml was used. A D-dimer result of >/= 500 ng FEU/ml was considered positive and a result of < 500 ng FEU/ml was considered negative.

This study was designed as a management clinical trial and patients were grouped according to PTP. Those patients having a negative D-dimer test result and a low or moderate PTP of DVT underwent no further diagnostic testing and were followed up for 3 months for development of DVT. Patients with a positive D-dimer test result and/or high PTP underwent serial compression ultrasound (CUS).

The overall prevalence of DVT in the total population studied was 10.1% (56/556). One sample from the original study was not tested due to volume limitations. The sensitivity, specificity and negative predictive value of the VIDAS D-Dimer New assay using a clinical cut off of 500 ng FEU/ml is summarized below with the corresponding 95% confidence intervals (CI).

**All Patients**

| Patients | N | % Clinical Sensitivity (95% CI) | % Clinical Specificity (95% CI) | % Negative Predictive Value (95% CI) |
|---|---|---|---|---|
| Suspected DVT All PTP's | 555 | 100.0 (56/56) (93.6– 100.0) | 32.9 (164/499) (28.8 – 37.2) | 100.0 (164/164) (97.8 – 100.0) |

**Patients with low PTP**

| Patients | N | % Clinical Sensitivity (95% CI) | % Clinical Specificity (95% CI) | % Negative Predictive Value (95% CI) |
|---|---|---|---|---|
| Suspected DVT with Low PTP | 295 | 100.0 (18/18) (81.5– 100.0) | 39.7 (110/277) (33.9 – 45.7) | 100.0 (110/110) (96.7 – 100.0) |

**Patients with moderate PTP**

| Patients | N | % Clinical Sensitivity (95% CI) | % Clinical Specificity (95% CI) | % Negative Predictive Value (95% CI) |
|---|---|---|---|---|
| Suspected DVT with Moderate PTP | 189 | 100.0 (17/17) (80.5– 100.0) | 26.7 (46/172) (20.3 – 34.0) | 100.0 (46/46) (92.3 – 100.0) |

**Patients with high PTP**

| Patients | N | % Clinical Sensitivity (95% CI) | % Clinical Specificity (95% CI) | % Negative Predictive Value (95% CI) |
|---|---|---|---|---|
| Suspected DVT with High PTP | 71 | 100.0 (21/21) (83.9– 100.0) | 16.0 (8/50) (7.2 – 29.1) | 100.0 (8/8) (63.1 – 100.0) |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 2 2003

Ms. Sandra Perreand
Director, Regulatory Affairs
BioMérieux, Inc.
595 Anglum Road
Hazelwood, Missouri 63042

Re: k030328
Trade/Device Name: VIDAS® D-Dimer New Assay
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fivrinogen and Fibrin Split Products, Antigen, Antiserum, Control
Regulatory Class: II
Product Code: DAP
Dated: July 21, 2003
Received: July 21, 2003

Dear Ms. Perreand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):**

**Device Name:** VIDAS D-Dimer New (DD2) Assay

**Indications for Use:**

VIDAS® D-Dimer New is an automated, quantitative test for use on the VIDAS analyzer for the immunoenzymatic determination of cross-linked fibrin degradation products (FbDP) containing the D-dimer domain in citrated human plasma using the Enzyme Linked Fluorescent Assay (ELFA) technique. VIDAS D-Dimer New is indicated for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) in outpatients suspected of DVT or PE.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tuy Lo V

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030328