510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K030328

B. Analyte:
D-Dimer

C. Type of Test:
Quantitative, enzyme-linked fluorescent Immunoassay

D. Applicant:
bioMerieux, Inc.

E. Proprietary and Established Names:
VIDAS D-DIMER NEW (DD2) ASSAY

F. Regulatory Information:

1. Regulation section:
   21 CRD 864.7320

2. Classification:
   Class II

3. Product Code:
   DAP

4. Panel:
   81 Hematology

G. Intended Use:

1. Indication(s) for use:
   The 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.

2. Special condition for use statement(s):
   The VIDAS®D-Dimer New is indicated for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude deep vein thrombosis (DVT) in outpatients suspected of DVT.

3. Special instrument Requirements:

   The VIDAS®D-Dimer New is intended for use on the VIDAS analyzer

H. Device Description:

The VIDAS®D-Dimer New (DD2) is an automated, quantitative test for d-dimer, intended for use on the VIDAS analyzer (K891385). Fibrin degradation products (FbDP) in human plasma are determined 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.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   VIDAS D-Dimer (DD) New Assay

2. Predicate K number(s):
   K020810
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Sample requirements	Citrated plasma	Same
Differences		
Item	**Device**	**Predicate**
Indications for use	To exclude DVT in conjunction with a PTP	Aid in diagnosis of DVT and PE

J. Standard/Guidance Document Referenced (if applicable):

K. Test Principle:

enzyme-linked fluorescent immunoassay (ELFA)

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

			Within-run Precision	Total Precision
Plasma	N	Conc. (ng FEU/ml)	CV (%)	CV (%)
Level 1	80	264	5.0	5.7
Level 2	80	549	3.9	5.8
Level 3	80	7283	5.3	7.1

b. Linearity/assay reportable range:
45 – 10,000 ng FEU/ml

c. Traceability (controls, calibrators, or method):

d. Detection limit:
45 ng FEU/ml

e. Analytical specificity:

f. Assay cut-off:
500 ng FEU/ml

2. Comparison studies:
   a. Method comparison with predicate device:

   b. Matrix comparison:

3. Clinical studies:
   a. Clinical sensitivity:
   100% (95% CI, 95.0-100)

   b. Clinical specificity:
   33% (95% CI, 27.0-39.1)

   c. Other clinical supportive data (when a and b are not applicable):
   Negative predictive value 100% (95% CI, 95.3-100)

4. Clinical cut-off:
   500 ng FEU/ml

5. Expected values/Reference range:
   <500 ng FEU/ml

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) (33.8-45.7)	100.0 (110/110) (96.7-100.0)
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)
Suspected DVT with High PTP	71	100.0 (21/21) (83.9-100.0)	18.0 (8/50) (7.2-29.1)	100.0 (8/8) (83.1-100.0)

M. Conclusion:

Data has demonstrated that this device is substantially equivalent to a legally marketed device.