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

A. 510(k) Number:
   #K032017
B. Analyte:
   D-Dimer
C. Type of Test:
   N/A
D. Applicant:
   Bio-Rad Laboratories
E. Proprietary and Established Names:
   Liquichek™ D-dimer Control, Levels 1, 2 and 3
F. Regulatory Information:
   1. Regulation section:
      21 CFR Section 864.5425 – Multipurpose System for in vitro Coagulation
                                       Studies
   2. Classification:
      Class II
   3. Product Code:
      GGN – Coagulation Control Plasma
   4. Panel:
      Hematology (81)
G. Intended Use:
   1. Intended use(s):
      Liquichek™ D-dimer Control is intended for use as an assayed quality control
      to monitor the precision of laboratory testing procedures for D-dimer.
   2. Indication(s) for use:
      This control is for use with the following test methods: bioMerieux Vidas;
      Dade Behring Stratus CS, BCS/BCT and Sysmex Series – Advanced D-
      Dimer; Diagnostica Stago Sta/Sta-R/Sta-Compact – LIATEST; IL ACL
      Series; Roche Hitachi and Cobas Integra 400/800 – Tina-quant.
   3. Special condition for use statement(s):
      N/A
   4. Special instrument Requirements:
      Instrumentation listed under Indications for Use.
H. Device Description:
   Liquichek™ D-dimer Control is a liquid coagulation control prepared from processed
   human plasma with added constituents of human/animal origin and preservatives.
I. Substantial Equivalence Information:
   1. Predicate device name(s):
      Bio-Rad Laboratories Liquichek™ D-dimer Control, Levels 1 and 2
   2. Predicate K number(s):
      #K030182

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	See above	Same
Matrix	Liquid human plasma	Same
Stability	(3) years at 2º – 8º C.; (30) days at 2º – 25º C.	Same
Differences		
Item	**Device**	**Predicate**
Levels	Tri-level	Bi-level

J. Standard/Guidance Document Referenced (if applicable):
   N/A
K. Test Principle:
   See test methods for various instruments under Indications for Use.
L. Performance Characteristics (if/when applicable):
   1. Analytical performance:
       a. *Precision/Reproducibility:*

       b. *Linearity/assay reportable range:*

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

       d. *Detection limit:*

       e. *Analytical specificity:*

       f. *Assay cut-off:*

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

       b. *Matrix comparison:*

   3. Clinical studies:
       a. *Clinical sensitivity:*

       b. *Clinical specificity:*

       c. *Other clinical supportive data (when a and b are not applicable):*

   4. Clinical cut-off:

   5. Expected values/Reference range:

M. Conclusion:

This device is substantially equivalent to a legally marketed device. The sponsor provided value assignment protocols and data forms for the individual manufacturers and reference laboratories used to generate data.

They recommended at least (20) replicates for each level of quality control plasma, from separate assays over a period of (10) days, using multiple reagent lots. They required submission of the raw data obtained from the instruments used to generate the means and ranges displayed on the assay sheet.

In addition the sponsor submitted real-time stability data summaries for (3) lots of the quality control plasma. Results were within acceptable analytical limits for this kind of device.