

AUG - 8 2003

K 032017

Summary of Safety and Effectiveness  
Liquichek™ D-dimer Control

1.0 **Submitter**

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**Contact Person**

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Regulatory Affairs Specialist  
Telephone: (949) 598-1367

**Date of Summary Preparation**

June 26, 2003

2.0 **Device Identification**

Product Trade Name: Liquichek™ D-dimer Control  
Common Name: Plasma, Coagulation Control  
Classifications: Class II  
Product Code: GGN  
Regulation Number: CFR 862.5425

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek™ D-dimer Control  
Bio-Rad Laboratories  
Irvine, California

510(k) Number: **K030182**

4.0 **Description of Device**

Liquichek™ D-dimer Control is prepared from processed human plasma with added constituents of human and animal origin, and preservatives. The control is provided in liquid form for convenience.

5.0 **Statement of Intended Use**

Liquichek™ D-dimer Control is intended for use as an assayed quality control to monitor the precision of laboratory testing procedures for D-dimer.

## 6.0 Comparison of the new device with the Predicate Device

The new Liquichek™ D-dimer Control claims substantial equivalence to the Liquichek™ D-dimer Control currently in commercial distribution (**K030182**). The new Liquichek™ D-dimer Control is a tri-level (Level 1, 2 and 3) product and the current product is a bi-level (Level 1 and 2) product.

**Table 1.** Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ D-dimer Control (New Device)	Bio-Rad Liquichek™ D-dimer Control (Predicate Device K030182)
<b>Similarities</b>		
<b>Intended Use</b>	Liquichek D-dimer Control is intended for use as a quality control to monitor the precision of D-dimer procedures.	Liquichek D-dimer Control is intended for use as a quality control to monitor the precision of D-dimer procedures.
<b>Analytes</b>	D-dimer	D-dimer
<b>Storage (Unopened)</b>	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
<b>Matrix</b>	Processed human plasma with added constituents of human and animal origin, and preservatives.	Processed human plasma with added constituents of human and animal origin, and preservatives.
<b>Open Vial Claim</b>	30 days at 2 to 25°C	30 days at 2 to 25°C
<b>Form</b>	Liquid	Liquid
<b>Differences</b>		
<b>Levels</b>	Level 1, 2 and 3	Level 1 and 2 (Does not have a Level 3 product)
<b>Analyte D-dimer Levels</b>	Level 3: 4.5 – 5.5 ug FEU/mL	Level 1: 0.22 - 0.4 ug FEU/mL Level 2: 1.5 – 2.5 ug FEU/mL

## 7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ D-dimer Control. Product claims are as follows:

- 7.1 Open vial: Once the product is opened, the analyte will be stable for 30 days when stored tightly capped at 2 to 25°C.
- 7.2 Shelf Life: Three years when stored at 2 to 8 °C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG - 8 2003

Ms. Maria Zeballos  
Regulatory Affairs Specialist  
Bio-Rad Laboratories  
9500 Jeronimo Road  
Irvine, California 92618-2017

Re: k032017  
Trade/Device Name: Liquichek™ D-dimer Control  
Regulation Number: 21 CFR § 864.5425  
Regulation Name: Multipurpose System for in vitro coagulation studies  
Regulatory Class: II  
Product Code: GGN  
Dated: June 26, 2003  
Received: July 1, 2003

Dear Ms. Zeballos:

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.

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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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

510 (k) Number (if known): \_\_\_\_\_

Device Name: **Liquichek™ D-dimer Control**

Indications for Use:

**Liquichek D-dimer Control is intended for use as an assayed quality control to monitor the precision of laboratory testing procedures for D-dimer.**

**Methods:**

- bioMerieux Vidas
- Dade Behring BCS/BCT – Advanced D-Dimer
- Dade Behring Stratus CS
- Dade Behring Sysmex Series – Advanced D-Dimer
- Diagnostica Stago Sta/Sta-R/Sta-Compact – LIATEST
- IL ACL Series
- Roche Cobas Integra 400/800 – Tina-quant
- Roche Hitachi – Tina-quant

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

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*Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription use ✓ or Over-the Counter use \_\_\_\_\_

*Janette G. Michalek MD* FOR *J. BALTISTA*  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) *K032017*