Summary of Safety and Effectiveness
Liquichek™ TDM 1, 2, 3

K012741 9/12/01

1.0 Submitter

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Date of Summary Preparation

August 15, 2001

2.0 Device Identification

Product Name:	Liquichek™ TDM 1, 2, 3
Common Name:	Drug Mixture Control Materials
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 Device to Which Substantial Equivalence is Claimed

Original 510(k) Name: Kit Ciba Corning L-TDM Control I, II, III
Current Name: Liquichek™ TDM 1, 2, 3
Bio-Rad Laboratories
Irvine, California

Docket Number: K893682

4.0 Description of Device

Liquichek™ TDM is prepared from human serum, with added constituents of nonhuman protein, drugs and preservatives. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek™ TDM is intended for use as an assayed quality control serum to monitor the precision of laboratory procedures and other analytes listed in the package insert.

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6.0 Comparison of the new device with the Predicate Device

The new Liquichek™ TDM 1, 2, 3 claims substantial equivalence to the Liquichek™ TDM currently in commercial distribution (K893682). The new Liquichek™ TDM 1, 2, 3 contains preservatives and the current product does not.

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

Characteristics	Bio Rad Liquichek™ TDM 1, 2, 3 (New Device)	Bio Rad Liquichek™ TDM 1, 2, 3 (Predicate Device)
SIMILARITIES		
Intended Use	Liquichek TDM is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Liquichek TDM is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened Frozen)	–20°C or colder until expiration date	–20°C or colder until expiration date
Analytes	Same as Predicate (see insert)	Same as new device (see insert)
DIFFERENCES		
Storage (Unopened Thawed)	2-8° C for 180 days Exceptions: Cortisol, Desipramine, T_4 total and T_3 free are stable for 30 days.	2-8° C for 180 days Exceptions: Clonazepam, Cortisol, Desipramine, and free T_4 are stable for 30 days.
Open Vial Claim	2-8° C for 30 days. Exceptions: T_3 total and T_3 free will be stable for 15 days and Diazepam will be stable for 24 hours days.	2-8° C for 30 days. Exceptions: T_3 will be stable for 15 days and Diazepam will be stable for 24 hours days.
Preservatives and Stabilizers	Preservatives are added.	No preservatives or stabilizers were added

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ TDM 1, 2, 3. Product claims are as follows:

7.1 Open vial: Once the control is thawed and opened, all analytes will be stable for 30 days when stored tightly capped at 2-8°C, with the following exceptions: T_3 total and T_3 free will be stable for 15 days and Diazepam will be stable for 24 hours days.

Avoid repeated freezing and thawing of the quality control material.

7.2 Closed Vial: When the control material is thawed and stored unopened at 2-8° C all analytes will be stable for 180 days with the following exceptions: Cortisol, Desipramine, and T_4 total and T_3 free are stable for 30 days

7.3 Shelf Life: 36 months when stored at –20 °C or colder

Real time studies to support the shelf life of this product are available.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: k012741
Trade/Device Name: Liquichek™ TDM 1, 2, 3
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: Class I, reserved
Product Code: DIF
Dated: August 15, 2001
Received: August 16, 2001

Dear Ms. Platt:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K012741

Device Name: **Liquichek™ TDM 1, 2, 3**

Indications for Use:

Liquichek TDM is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____

Kevin Alexander for Susan Cruzen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012741