OCT 14 2004

K042336

Summary of Safety and Effectiveness

Meter Trax Control

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

Maria Zeballos
Regulatory Affairs Specialist
Telephone: (949) 598-1367

Date of Summary Preparation

August 25, 2004

2.0 **Device Identification**

Product Trade Name:	Meter Trax Control
Common Name:	Hematology and Pathology Devices (Hematology quality control mixture)
Classifications:	Class II
Product Code:	JPK
Regulation Number:	21 CFR 864.8625

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

Meter Trax is an assayed whole blood control used in monitoring the precision of laboratory procedures for glucose, hemoglobin and hematocrit testing. This control is substantially equivalent to the following quality control materials that are currently in the market:

Meter Trax
Bio-Rad Laboratories (formerly Hematronix, Inc.)
Plano, Texas 75074
510 (k) Number: K904461

4.0 **Description of Device**

Meter Trax Control is a suspension of stabilized human red blood cell components with added constituents of animal origin, chemicals, stabilizers, and preservatives. This product is provided in liquid form for convenience.

Intended Use

Meter Trax is an assayed whole blood control used in monitoring the precision of laboratory procedures for glucose, hemoglobin and hematocrit testing.

5.0 Comparison of the new device with the Predicate Device

Meter Trax Control is substantial equivalent to Meter Trax (K904461) currently in commercial distribution. The similarities and differences are listed below.

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

Characteristics	Bio-Rad Meter Trax Control (New Device)	Bio-Rad Laboratories (formerly Hematronix, Inc.) Meter Trax (Predicate Device K904461)
Similarities		
Matrix	Human Whole Blood based	Human Whole Blood based
Stabilizers	Contains stabilizers	Does not contain stabilizers
Form	Liquid	Liquid
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Open vial Stability	Hematocrit: 31days at 2 to 8°C Glucose and Hemoglobin: 31days at 2 to 8°C or 18 to 30°C	Hematocrit: 31days at 2 to 8°C Glucose and Hemoglobin: 31days at 2 to 8°C or 18 to 30°C
Analytes	Contains the following parameters: Glucose Hemoglobin Hematocrit	Contains the following parameters: Glucose Hemoglobin Hematocrit
Differences		
Intended Use	Meter Trax is an assayed whole blood control used in monitoring the precision of laboratory procedures for glucose, hemoglobin and hematocrit testing.	Meter Trax™ Control is intended for use as a whole blood reference control for glucose, hemoglobin, and hematocrit.

1.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Meter Trax Control. Product claims are as follows:

1.1 Open vial Stability:

Claims: Hematocrit will be stable for 31 days at 2 to 8°C.
Glucose and Hemoglobin will be stable for 31 days at 2 to 8°C or 18 to 30°C.

1.2 Shelf Life Stability

Claims: 180 days at 2 to 8°C

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 14 2004

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

Re: k042336
Trade/Device Name: Meter Trax Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: Class II
Product Code: JPK, JJY
Dated: August 25, 2004
Received: August 30, 2004

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.

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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042336

Device Name: **Meter Trax Control**

Indications For Use: **Meter Trax is an assayed whole blood control used in monitoring the precision of laboratory testing procedures for the analytes listed in this package insert.**

The following parameters are listed in the package insert:

- Glucose
- Hemoglobin
- Hematocrit

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042336