

K070200

MAR 19 2007

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7688

Contact Person: Dimitris Demirtzoglou

Date Prepared: January 19, 2007

2) Device name **Proprietary name:** TDM Control Set
Common name: Quality control material (assayed and unassayed).
Classification name: Multi-analyte controls, all kinds (assayed and unassayed)

3) Predicate devices We claim substantial equivalence to the currently marketed TDM Control Set (K060429).

4) Device Description The TDM Control Set contains liquid controls based on human serum with added therapeutic drugs, preservative, and stabilizer. The adjusted concentrations and activities of the control components are usually in the normal range or at the normal/pathological threshold. Some of the methods as specified in the enclosed value sheet may not be available in all countries.

The TDM Control Set contains a mixture of 17 different drugs. Drugs included are acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, N-acetylprocainamide, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid and vancomycin

The concentrations and activities of the components are lot-specific. The exact values are given in the enclosed value sheet.

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510(k) Summary, Continued

5.) Intended Use The TDM Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.

6.) Comparison to the Predicate Device Below the similarities and differences between the modified TDM Control Set and its predicate device [TDM Control Set (K060429)] are presented. The device will continue to be sold under the same name, TDM Control Set.

The TDM Control Set contains liquid controls based on human serum with added therapeutic drugs, preservative, and stabilizer. The TDM Control Set contains a mixture of 17 different drugs. Drugs included are acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, N-acetylprocainamide, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid and vancomycin.

The control set contains three levels for each drug. In addition, the TDM Control Set is value assigned for two levels (level I & II) of serum barbiturates, utilizing phenobarbital already present in the controls.

The predicate device, TDM Control Set (K060429) is identical with the current TDM Control set except that it is not value assigned fo two levels of serum barbiturates.

No new analytes were added, and no drug levels have changed. Therefore, stability and composition have not changed. The package insert and intended use have not changed, but the value assignment for serum barbiturates was added to the value sheet. The traceability of the controls has not changed, except of course for the serum barbiturates assignment.

Here is a summary of the TDM Control Set in relation to serum barbiturates:

The TDM Control Set contains phenobarbital. The controls were tested using the Serum Barbiturates assay. The Serum Barbiturates assay is calibrated with secobarbital, with cross-reactivity to phenobarbital of approximately 26%. Essentially, we are using the cross-reactivity of the phenobarbital in the controls to allow us to assign targets for the Serum Barbiturates assay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Roche Diagnostics Corp.
9115 Hague Road, PO Box 50416
Indianapolis, IN 46250-0457
ATTN: Mr. Dimitris Demirtzoglou

MAR 19 2007

Re: k070200
Trade/Device Name: TDM Control Set
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I (reserved)
Product Code: JJY
Dated: March 06, 2007
Received: March 07, 2007

Dear Mr. Demirtzoglou:

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).

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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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070200

Device Name: TDM Control Set

Indications For Use:

The TDM Control Set is intended for use as an assayed quality control product on Roche/Hitachi and COBAS INTEGRA analyzers. Two assayed levels of serum barbiturates and three assayed levels of acetaminophen, amikacin, carbamazepine, digoxin, gentamicin, lidocaine, N-acetylprocainamide, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid and vancomycin are provided.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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

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