AUG - 6 2003

510(k) Summary

K031856

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) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: June 13, 2003

2) Device name

Proprietary name: Preciset TDM I and Preciset TDM II Calibrators

Common name: Calibrators, Drug Mixture

Classification name: Clinical Toxicology Calibrator

3) Predicate devices

We claim substantial equivalence to the currently marketed Roche calibrators:

Cobas-FP Digoxin Calibrators, K851032
Cobas-FP Carbamazepine Calibrators, K850807
Cobas-FP Gentamicin Calibrators, K843827 and K945523
Cobas-FP Phenytoin Calibrators, K936131
Cobas-FP Phenobarbital Calibrators, K936130
Cobas-FP Primidone Calibrators, K852318
Cobas-FP Theophylline Calibrators, K871484
Cobas-FP Tobramycin Calibrators, K843828
Cobas-FP Valproic Acid Calibrators, K925003
Cobas-FP Vancomycin Calibrators, K901759
Roche TDM ONLINE Digitoxin Calibrators, K972250
Cobas-FP Amikacin Calibrators, K852317
Cobas-FP Lidocaine Calibrators, K853010
Cobas-FP NAPA Calibrators, K871680
Cobas-FP Procainamide Calibrators, K852320 and K942847/S2
Cobas-FP Quinidine Calibrators, K941440

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4) Device Description

Roche Preciset TDM I calibrators contain a mixture of 10 different drugs, prepared by the quantitative addition of drug to human serum, with the addition of a stabilizer and preservative. The calibrator set contains six levels for each drug contained in bottles A-F. Bottle A is negative (drug free) human serum, followed by bottles B-F containing increasing amounts of each drug in a multi-analyte mixture. A single bottle containing 10 ml of drug-free human serum is also provided as a diluent. Drugs and their respective levels included are as follows:

Digoxin: 0, 0.5, 1, 2, 3, 5 ng/ml
Carbamazepine: 0, 1.25, 2.5, 5, 10, 20 µg/ml
Gentamicin: 0, 0.5, 1.5, 4, 7, 10 µg/ml
Phenytoin: 0, 2.5, 5, 10, 20, 40 µg/ml
Phenobarbital: 0, 5, 10, 20, 40, 60 µg/ml
Primidone: 0, 2, 4, 8, 16, 24 µg/ml
Theophylline: 0, 2.5, 5, 10, 20, 40 µg/ml
Tobramycin: 0, 1, 2, 4, 7, 10 µg/ml
Valproic Acid: 0, 12.5, 25, 50, 100, 150 µg/ml
Vancomycin: 0, 5, 10, 20, 40, 80 µg/ml

Roche Preciset TDM II calibrators contain a mixture of 6 different drugs, prepared by the quantitative addition of drug to human serum, with the addition of a stabilizer and preservative. Drugs included are Digitoxin, Amikacin, Lidocaine, NAPA, Procainamide, and Quinidine. This calibrator set also provides six levels for each drug contained in bottles A-F. Bottle A is negative (drug free) human serum, followed by bottles B-F containing increasing amounts of each drug in a multi-analyte mixture. A single bottle containing 10 ml of drug-free human serum is also provided as a diluent. Drugs and their respective levels included are as follows:

Digitoxin: 0, 7.5, 15, 30, 45, 65 ng/ml
Amikacin: 0, 2.5, 5, 10, 20, 40 µg/ml
Lidocaine: 0, 0.5, 1, 2.5, 5, 10 µg/ml
NAPA: 0, 2.5, 5, 10, 20, 30 µg/ml
Procainamide: 0, 1, 2, 4, 8, 16 µg/ml
Quinidine: 0, 0.5, 1, 2, 4, 8 µg/ml

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5.) Intended Use

The **Preciset TDM I** calibrators are designed for the calibration of the Roche assays for the quantitative determination of digoxin, carbamazepine, gentamicin, phenytoin, phenobarbital, primidone, theophylline, tobramycin, valproic acid and vancomycin in human serum and plasma on automated clinical chemistry analyzers.

The **Preciset TDM II** calibrators are designed for the calibration of the Roche assays for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide and quinidine in human serum and plasma on automated clinical chemistry analyzers.

6.) Comparison to the Predicate Device

The Roche Preciset TDM I and Preciset TDM II multianalyte calibrators are substantially equivalent to other products in commercial distribution intended for similar use. Most notably, they are substantially equivalent to the currently marketed Roche single analyte TDM calibrators (listed in section 3 above) for the same drugs and at the same levels.

The Roche Preciset TDM I and Preciset TDM II multianalyte calibrators are prepared by the quantitative addition of drugs to human serum with an added stabilizer and preservative. Drugs are added in the same quantities as the predicate, single analyte TDM calibrators. The new multianalyte calibrators provide a more convenient calibrator set for multiple TDM assays than the predicate, single analyte TDM calibrator sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

AUG - 6 2003

Re: k031856
Trade/Device Name: Roche Preciset TDM I and Preciset TDM II Calibrators
Regulation Number: 21 CFR § 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: II
Product Code: DKB
Dated: June 13, 2003
Received: June 16, 2003

Dear Mr. Kaufman:

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,

Steven Gutman

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

Indications for Use Statement

510(k) Number (if known): K031856

Device Name: Roche Preciset TDM I and Preciset TDM II Calibrators

Indications for Use:

The Preciset TDM I calibrators are designed for the calibration of the Roche assays for the quantitative determination of digoxin, carbamazepine, gentamicin, phenytoin, phenobarbital, primidone, theophylline, tobramycin, valproic acid and vancomycin in human serum and plasma on automated clinical chemistry analyzers.

The Preciset TDM II calibrators are designed for the calibration of the Roche assays for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide and quinidine in human serum and plasma on automated clinical chemistry analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Devi
Evaluation and Safety

510(k) K031856