K971060

JUL - 7 1997

BOEHRINGER MANNHEIM CORPORATION

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

Boehringer Mannheim Corporation
2400 Bisso Lane
Concord, CA 94524-4117
(510) 674-0690 extension 8413
Fax number: (510) 687-1850

Contact Person: Yvette Lloyd

Date Prepared: March 20, 1997

2. Device Name

Proprietary name: Precinorm® TDM Controls

Common name: Controls

Classification name: Single (specified) analyte controls (assayed + unassayed)

3. Predicate device

The Boehringer Mannheim Precinorm® TDM Controls are substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Baxter Dade® IAC-X Comprehensive Immunoassay Control (K912455).

4. Device Description

The Boehringer Mannheim Precinorm® TDM Controls are manufactured using human serum albumin, therapeutic drugs, stabilizers, and preservatives. The analytes are appropriately spiked into the control matrix to the correct control concentration levels. The controls are in process checked, and a value assignment process is done via a comparison to an analyte specific (and chemistry specific) calibrator.

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5. Intended use

The Boehringer Mannheim Precinorm® TDM Controls are used to monitor accuracy and precision.

6. Comparison to predicate device

The Boehringer Mannheim Precinorm® TDM Controls are substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the Baxter Dade® IAC-X Comprehensive Immunoassay Control (K912455).

The following table compares the Boehringer Mannheim Precinorm® TDM Controls with the predicate device, the Baxter Dade® IAC-X Comprehensive Immunoassay Controls. Specific data on the performance of the controls have been incorporated into the draft labeling in attachment 5. Labeling for the predicate devices are provided in attachment 6..

Similarities:

- Similar intended use
- Similar matrix
- Similar stability claims
- Both are tri-level

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510(k) Summary, Continued

Differences:

Feature	Precinorm® TDM Control	Baxter-Dade® Immunoassay Control
Analytes	T4, T-Uptake, T3, Amikacin, Carbamazepine, Hydrocortisone (Cortisol), Quinidine, Digoxin, Digitoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Phenobarbital, Phenytoin, Primidone, Procainamide, N-acetylprocainamide, Theophylline, Tobramycin, Valproic Acid, Methotrexate, Chloramphenicol, Salicylic Acid, Lithium, Acetaminophen, Propanolol, Vancomycin, and Streptomycin.	Acetaminophen, Alpha-Fetoprotein (AFP), Aldosterone, Amikacin, Carbamazepine, Carcinoembryonic Antigen (CEA), Cortisol, Cyclosporine, Digoxin, Disopyramide, Estradiol, Ethosuximide, Ferritin, Folate, Free T3, Free T4, Follicle Stimulating Hormone (FSH), Gentamicin, Human Chorionic Gonadotropin, (hCG), Human Growth Hormone (hGH), Human Luteinizing Hormone (hLH), Immunoglobulin E (IgE), Insulin, Iron Binding Capacity, Lidocaine, Lithium, N-acetylprocainamide (NAPA), Prostatic Acid Phosphatase (PAP), Phenobarbital, Phenytoin, Primidone, Procainamide, Progesterone, Prolactin, Prostate Specific Antigen (PSA), Parathyroid Hormone (PTH), Quinidine, Salicylate, Serum Iron, Tricyclic Antidepressants (TCA), Testosterone, Theophylline, Thyroid Uptake/T3 Uptake, Tobramycin, Total T3, Total T4, TSH, Valproic Acid, Vancomycin, Vitamin B12
Reconstitution Instructions	Add 3 mL of distilled water, then let sit for 30 minutes, with occasional swirling.	Add 5 mL of distilled or deionized water, then let stand at room temperature for 10 minutes.

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6. Comparison to predicate device, (cont.)

Performance Characteristics:

• Dose assignment and stability: equivalent performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Yvette R. Lloyd
Regulatory Affairs Specialist
Boehringer Mannheim Corporation
2400 Bisso Lane
P.O. Box 4117
Concord, California 94524-4117

JUL - 7 1997

Re: K971060
Precinorm™ TDM Controls
Regulatory Class: I
Product Code: DIF
Dated: June 20, 1997
Received: June 23, 1997

Dear Ms. Lloyd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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):

Device Name: Precinorm® TDM Control

Indications For Use:

Precinorm® TDM is a triple range lyophilised control material based on human serum.

Precinorm® TDM is used for monitoring accuracy or precision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971060

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)