K062972

OCT 13 2006

510(k) Summary–Precinorm CK-MB & Precipath CK-MB

Introduction

Roche Diagnostics Corporation hereby submits this Special 510(k): Device Modification to provide notification of modifications to our Precinorm CK-MB Control. This control was originally cleared for use in K003158, along with a CK-MB reagent and calibrator system on Roche/Hitachi Analyzers.

Modifications to the control include:

- Change of name for Precinorm CK-MB to Precipath CK-MB (no change of analyte concentration), and
- New, additional control level with reduced levels of CK and CK-MB to normal levels. This new level is now called Precinorm CK-MB.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-7637

Contact person: Kerwin Kaufman

Date prepared: September 28, 2006

Device Name

Proprietary name: Precinorm CK-MB and Precipath CK-MB Controls

Common name: Single (Specified) Analyte Controls (assayed and unassayed)

Classification name: Quality control material (assayed and unassayed)

Device Description

Precinorm CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet. Precipath CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Precinorm CK-MB is a lyophilized controls based on bovine serum albumin. Adjusted activities of the control components are usually in the normal range or at the normal/pathological threshold. Precipath CK-MB is a lyophilized controls based on bovine serum albumin. Adjusted activities of the control components are usually in the pathological range. Biological additives for both control levels include CK-MM from human origin and CK-BB from porcine brain.

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Continued

Intended use

Precinorm CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Precipath CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Predicate Device

We claim substantial equivalence to the Precinorm CK-MB control cleared in K003158.

Substantial equivalency – Similarities/Differences

The table below indicates the similarities and differences between the modified Precinorm CK-MB control and its predicate device (Precinorm CK-MB, K003158). Note that the predicate device is now sold as Precipath CK-MB (no change in analyte concentration) as described above.

Feature	Predicate device: Precinorm CK-MB (K003158)	Modified device: Precinorm CK-MB and Precipath CK-MB
Intended Use (from labeling)	Precinorm CK-MB is for use in the quality control of Roche methods for the quantitative determination of CK-MB and creatine kinase activities. The control is used for monitoring accuracy and precision both for manual techniques and for assays on clinical chemistry analyzers.	Precinorm CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet. Precipath CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.
Reagent composition	Lyophilized control serum based on bovine serum albumin with chemical additives and material of biological origin.	Same

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Continued

Substantial equivalency – Similarities/Differences (continued)

Feature	Predicate device: Precinorm CK-MB (K003158)	Modified device: Precinorm CK-MB and Precipath CK-MB
Active Ingredient Level	*Precinorm CK-MB*: CK and CK-MB usually at pathological level	*Precinorm CK-MB*: CK and CK-MB usually at normal range or at the normal/pathological threshold. *Precipath CK-MB*: CK and CK-MB usually at pathological level
Stability - shelf life and open vial	2-8 °C until expiration date Reconstituted: 24 hours at 25° C 3 days at 4° C 1 month at -20° C (freeze only once)	Same Same
Traceability	Traceability of the target values is given in the respective instructions for use of the system reagent to be used in combination with the recommended calibrator.	Same
Value Assignment	The value assignment takes place in three internal laboratories. Each laboratory runs at least three independent series. An independent series includes full calibration using a new calibrator vial and sample vial. The mean is used as setpoint. Controls which have to be assigned are used as samples. The master calibrator is used for calibration.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kerwin Kaufman
Roche Diagnostics
PO Box 50457
9115 Hague Rd
Indianapolis, IN 46250

OCT 13 2006

Re: k062972
Trade/Device Name: Precinorm CK-MB and Precipath CK-MB Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: September 28, 2006
Received: September 29, 2006

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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):

Device Name: **Precinorm CK-MB and Precipath CK-MB Controls**

Indications For Use:

Precinorm CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Precipath CK-MB is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

The Precinorm CK-MB and Precipath CK-MB are assayed quality control material intended for medical purposes for use in Roche test systems to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation.

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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

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