SEP 1 2010 K102016

510(k) Summary – PreciControl ClinChem Multi 1 and 2

Introduction

Roche Diagnostics Corporation hereby submits this 510(k) to provide notification of our intent to market new controls named PreciControl ClinChem Multi 1 and 2.

Submitter name, address, contact

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Contact Person: Patrick Stimart

Date prepared: July 16, 2010

Device Name(s)

Proprietary name(s): 1. PreciControl ClinChem Multi 1 and 2

Common name(s): PCCC Multi 1 and 2

Classified under 21 CFR 862.1660

Classification name(s): Multi-analyte controls, all kinds (assayed and unassayed)

Product Code: JJY

Device Description

The PreciControl ClinChem Multi 1 and 2 are quality control products consisting of lyophilized human sera with constituents added as required to obtain desired component levels. Concentrations of the components in the controls have been adjusted to represent normal and pathological levels. The concentrations of the components in the controls are lot-specific and representative values are given in the enclosed value sheets.

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510(k) Summary – PreciControl ClinChem Multi 1 and 2, Continued

Intended Use	PreciControl ClinChem Multi 1 and 2 are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Predicate Device	Roche claims substantial equivalence to the Roche Diagnostics Precinorm Universal Plus and Precipath Universal Plus (K042389).

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510(k) Summary – PreciControl ClinChem Multi 1 and 2,
Continued

Substantial equivalence - similarities

The following table compares the PreciControl ClinChem Multi 1 and 2 controls with the predicate device.

Characteristic	PreciControl ClinChem Multi 1 and 2 controls	Precinorm U plus and Precipath U plus controls (K042389)
Intended Use	PreciControl ClinChem Multi 1 and 2 are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.	Precinorm U plus and Precipath U plus are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Format	PreciControl ClinChem Multi 1 and 2 are lyophilized controls based on human serum. The adjusted concentrations and activities of the control components are in the normal and pathological ranges.	Precinorm U plus and Precipath U plus are lyophilized controls based on human serum. The adjusted concentrations and activities of the control components are usually in the normal and pathological ranges.
Stability	• Same • Same *Exceptions stated for total bilirubin, direct bilirubin, UIBC, and ALT	• Unopened: Stable at 2-8°C until expiration date. • Stability of components after reconstitution*: at 15–25 °C 12 hours at 2–8 °C 5 days at (-15)–(-25) °C 4 weeks (when frozen once) *Exceptions stated for total bilirubin, direct bilirubin and Bicarbonate
Traceability	Same	Traceability of the target values is given in the respective instructions for use of the system reagents.
Value Assignment	Same	Traceable through Master Lot to standards or reference methods.

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Substantial equivalence – differences

The following table compares the PreciControl ClinChem Multi 1 and 2 controls with the predicate device.

Constituent Analytes

PreciControl ClinChem Multi 1 and 2 controls	Precinorm U plus and Precipath U plus controls (K042389)
Same	Alanine aminotransferase, Albumin, Alkaline phosphatase, Amylase, Amylase pancreatic, Aspartate aminotransferase, Bilirubin direct, Bilirubin total, Calcium, Chloride, Cholesterol, Cholinesterase, Creatine kinase, Creatinine, Glucose, gamma Glutamyltransferase, Iron, Lactate, Lactate dehydrogenase, Lipase, Lithium, Magnesium, Phosphate, Potassium, Sodium, Total protein, Triglycerides, Unsaturated iron -binding capacity, Urea, Uric acid
Not included	Acid phosphatase, Aldolase, Bicarbonate, Copper, Digoxin, Glutamate dehydrogenase, alpha Hydroxybutyrate dehydrogenase, Leucine aminopeptidase, Phospholipids, Thyroxine, T-uptake
alpha 1 Acid glycoprotein, Antisteptolysin O, alpha 1 Antitrypsin, Apolipoprotein A-1, Apolipoprotein B, C Reactive protein, Ceruloplasmin, Complement C3c, Complement C4, Creatine kinase MB, HDL-Cholesterol, Haptoglobin, Immunoglobulin A, Immunoglobulin G, Immunoglobulin M, LDL-Cholesterol, Prealbumin, Transferrin, Ferritin	Not included

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Roche Diagnostics Corp.
c/o Mr. Patrick J. Stimart
Regulatory Affairs Consultant
9115 Hague Road, PO Box 50416
Indianapolis, IN 46250-0416

SEP 1 2010

Re: k102016
Trade Name: Precicontrol Clinichem Multi 1 and 2
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: July 16, 2010
Received: July 19, 2010

Dear Mr. Stimart:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, 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 Form

K102016

510(k) Number (if known): K102016

Device Name: PreciControl ClinChem Multi 1 and 2

Indications for Use:

PreciControl ClinChem Multi 1 and 2 are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

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 OF 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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