K040280

MAR 1 1 2004

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.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Sherri L Coenen

Date Prepared: February 6, 2004

Device Name

Proprietary name: Precinorm Proteins in Urine/CSF and Precipath Proteins in Urine/CSF Controls

Common name: Precinorm PUC Precipath PUC

Classification name: Multi-analyte Controls, All Kinds (assayed and unassayed)

Device Description

The Precinorm PUC and Precipath PUC Controls consist of a buffered aqueous solution with biological materials added as required to obtain desired component levels in either the normal or pathological range. Values for constituent analytes are provided in product labeling.

Intended use

Precinorm PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Precipath PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Substantial Equivalence

The Precinorm PUC and Precipath PUC Controls are substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostic Precinorm Protein Precipath Protein Controls. (K981401). The intended use of both devices is quality control of their respective test systems.

Substantial equivalence - similarities

The following table compares the Precinorm PUC and Precipath PUC Controls with the predicate device.

Feature	**Precinorm PUC Precipath PUC**	**Precinorm Protein Precipath Protein (Predicate Device)**
Intended Use	Precinorm PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet. Precipath PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.	Precinorm Protein and Precipath Protein are used for quality control of the quantitative determination of serum proteins. The controls are used for monitoring accuracy and precision both for manual techniques and for assays on automated clinical chemistry analyzers.
Format	Liquid ready-for-use control based on a buffered aqueous solution. Concentrations of control components have been adjusted to represent normal and pathological ranges.	Liquid ready-for-use control based on human serum. Concentrations of control components have been adjusted to represent normal and pathological ranges.
Stability	Same	• Unopened: Stable at 2-8°C until expiration date. • Opened: Stable for 4 weeks at 2-8°C.

Substantial equivalence – differences

Comparison of proposed Precinorm PUC and Precipath PUC Controls and predicate device.

Feature	Precinorm PUC Precipath PUC	Precinorm Protein Precipath Protein (Predicate Device)
Matrix	Buffered aqueous solution	Stabilized human serum

Constituent Analytes

Precinorm PUC Precipath PUC	Precinorm Proteins Precipath Proteins (Predicate Device)
Albumin	α1-acid glycoprotein
Creatinine	Albumin
Total Rrotein	α1-antitrypsin
Urine/CSF Protein	Antistreptolysin O
	C3c
	C4
	Ceruloplasmin
	C-Reactive Protein
	Ferritin
	Haptoglobin
	IgA
	IgG
	IgM
	Prealbumin
	Total Protein
	Transferrin

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 1 2004

Ms Sherri L. Coenen
Regulatory Affairs Associate
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k040280
Trade/Device Name: Precinorm PUC and Precipath PUC Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 6, 2004
Received: February 6, 2004

Dear Ms. Coenen:

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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 Statement

510(k) Number (if known): N/A K040280

Device Name: Precinorm PUC and Precipath PUC Controls

Indications For Use:

Precinorm PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Precipath PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

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

(Optional Format 1-2-96)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040280