NOV 24 1999

K993360

510(k) Summary – Precinorm® Universal Plus and Precipath® Universal Plus Control Sera

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 Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576 3723

Contact person: Priscilla A. Hamill

Date prepared: October 4, 1999

Predicate device

Roche Diagnostics Precinorm® Universal Plus and Precipath® Universal Plus Control Sera is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the currently marketed Roche Diagnostics Precinorm® Universal and Precipath® Universal Control Sera (K811832)

Device description

Roche Diagnostics Precinorm® Universal Plus and Precipath® Universal Plus Control Sera is a two level quality control product prepared from lyophilized human serum with addition of constituent analytes as required to obtain normal and pathological levels.

510(k) Summary – Precinorm® Universal and Precipath® Universal Plus Control Sera, continued

Intended use / Indication for use

Roche Diagnostics Precinorm® Universal Plus and Precipath® Universal Plus Control Sera is intended for quality control in the quantitative determination of substrates, electrolytes, lipids, enzymes, proteins, and drugs. The control is used for monitoring accuracy or precision for manual techniques and assays from Roche on automated clinical chemistry analyzers.

Substantial equivalence

The most important modification of the device presented in this submission is the inclusion of values for additional analytes. Similarities and differences are presented in detail below.

Substantial equivalence - similarities

The following table compares Precinorm® Universal Plus and Precipath® Universal Plus Human Serum Controls, with the predicate device (currently marketed modified Precinorm® Universal and Precipath® Universal Human Serum Controls.)

Comparison of Modified Device and Predicate Device

Characteristic	Precinorm® Universal Plus and Precipath® Universal Plus Control Sera (Modified Device)	Precinorm® Universal and Precipath® Universal Human Serum Controls (Predicate Device)
Intended Use	For quality control in the quantitative determination of substrates, electrolytes, lipids, enzymes, proteins, and drugs. The control is used for monitoring accuracy or precision for manual techniques and assays from Roche on automated clinical chemistry analyzers.	For control of chemistry assays. This control material is well suited for both manual and automated analytical procedures.
Format	Lyophilized pooled human sera with constituents added as required to obtain desired component levels	Lyophilized pooled human serum with constituents added as required to obtain desired component levels
Levels	Two levels	Two levels

Substantial equivalence - differences

The following table compares the modified device with the predicate device.

Characteristic	Precinorm® Universal Plus and Precipath® Universal Plus Control Sera (Modified Device)	Precinorm® Universal and Precipath® Universal Human Serum Controls (Predicate Device)
Stability	• Stable at 2-8° C until expiration date • Reconstituted: ✓ 2-8° C - 5 days ✓ 25° - 12 hrs ✓ -20° - 1 month, with exceptions as noted in labeling	• Stable at 2-8° C until expiration date • Reconstituted: ✓ 2-8° C - 2 days ✓ 10-24° - 8 hrs ✓ -20° - 1 month, with exceptions as noted in labeling

Substantial equivalence – differences – addition of constitutent analyte values

The new device includes values for additional analytes listed in the table below.

Additional analytes	
Albumin	Lithium
Bicarbonate	Magnesium
Gamma globulins	Salicylate
Copper	Total iron binding capacity
Digoxin	Thyroxine (T_4)
GLDH	T-Uptake
Arylamidase	Unsaturated iron-binding capacity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 24 1999

Ms. Priscilla A. Hamill
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K993360
Trade Name: Precinorm® Universal Plus and
Precipath® Universal Plus Control Sera
Regulatory Class: I
Product Code: JJY
Dated: October 4, 1999
Received: October 6, 1999

Dear Ms. Hamill:

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 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). 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 requirements, 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 at (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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~N/A~~ K993360

Device Name: Precinorm® Universal Plus and Precipath® Universal Plus Control Sera

Indications For Use:

For quality control in the quantitative determination of substrates, electrolytes, lipids, enzymes, proteins, and drugs. The control is used for monitoring accuracy or precision both for manual techniques and assays from Roche 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 ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Peter E Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993360