K041227

MAY 27 2004

510(k) Summary - Precinorm ® Universal and Precipath ® Universal 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
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa M. Ambrose

Date prepared: May 7, 2004

Device Name

Proprietary name: Roche Diagnostics Precinorm ® Universal and Precipath ® Universal Control Sera

Common name: Precinorm U / Precipath U

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

Device description

Precinorm ® U/ Precipath ® U is a two level quality control product consisting of lyophilized human sera with constituents added as required to obtain desired component levels

Intended use

Precinorm ® U/ Precipath ® U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet

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510(k) Summary - Precinorm ® Universal and Precipath ® Universal Control Sera ,Continued

Substantial Equivalence

Roche claims substantial equivalence to the currently marketed Roche Diagnostics Precinorm ® Universal and Precipath ® Universal Control Sera (K992900).

Substantial Equivalence – Device comparison

The table below compares Precinorm U/ Precipath U with the predicate device (currently marketed Precinorm U/ Precipath U).

Characteristic	Precinorm U/ Precipath U (Predicate device, K992900)	Precinorm U/ Precipath U (Modified Device)
Intended Use	For use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet	Same
Format	Lyophilized human sera with constituents added as required to obtain desired component levels	Same
Analyte source for albumin and total protein methods in Precinorm U	Human serum	Human serum and bovine plasma albumin
Analyte source for albumin and total protein methods in Precipath U	Human serum	Same
Levels	Two levels	Same
Stability	Lyophilized Stable at 2-8°C until expiration date Reconstituted: • 2 to 8°C : 5 days • 15 to 25 °C : 12 hours • -15 to -25°C : 1 month (when frozen once) Exceptions for total and direct bilirubin as noted in package insert.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 7 2004

Theresa M. Ambrose, Ph.D. RAC
Regulatory Affairs Principal
Roche Diagnostics Corp.
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: k041227
Trade/Device Name: Precinorm ® Universal and Precipath ® Universal Control Sera
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assay and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: May 7, 2004
Received: May 10, 2004

Dear Dr. Ambrose:

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

510(k) Number (if known): K041227

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

Indications For Use:

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

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

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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