K050026

JAN 3 1 2005

510(k) Summary – C.f.a.s. (Calibrator for Automated Systems) PUC (Proteins in Urine/CSF); Precinorm ® PUC and Precipath ® PUC

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: January 5, 2005
Device 1 Name	Proprietary name: Roche Diagnostics C.f.a.s. (Calibrator for automated systems) PUC (Proteins in Urine/CSF) Common name: C.f.a.s. PUC Classification name: Calibrator, multi-analyte mixture
Device 2 Name	Proprietary name: Roche Diagnostics Precinorm ® PUC (Proteins in Urine/CSF) and Precipath ® PUC (Proteins in Urine/CSF Common name: Precinorm ® PUC / Precipath® PUC Classification name: Multi-analyte controls, all kinds (assayed and unassayed)

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510(k) Summary, continued

Device 1 description	C.f.a.s. PAC is a liquid, ready-for-use calibrator consisting of a buffered aqueous solution with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in the product labeling.
Device 2 description	Precinorm ® PUC/ Precipath ® PUC is a liquid ready-for-use control based on a buffered aqueous solution. Concentrations of control components have been adjusted to represent normal and pathological ranges. Values for constituent analytes are provided in the product labeling.
Device 1 Intended use	C.f.a.s. PUC is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.
Device 2 Intended use	Precinorm ® PUC/ Precipath ® PUC is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet
Device 1 Substantial Equivalence	For C.f.a.s. PUC, Roche claims substantial equivalence to the currently marketed currently marketed C.f.a.s. PUC, K040264.
Substantial equivalence comparison – Device 1	The table below compares C.f.a.s. PUC with its predicate device (currently marketed C.f.a.s. PUC, K040264).

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510(k) Summary, continued

Characteristic	C.f.a.s. PUC (Predicate device, K040264)	C.f.a.s. PUC (Modified Device)
Intended Use	C.f.a.s. PUC is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.	Same
Format	Liquid ready-for-use calibrator based on a buffered aqueous solution. The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.	Same
Stability	Unopened Stable at 2-8°C until expiration date Opened: Stable at 2 to 8°C for 4 weeks	Same
Level	Single level	Same
Constituent Analytes with Assigned Values	• Albumin • Total protein	• Albumin • Total protein • Immunoglobulin G

Device 2 Substantial Equivalence

For Precinorm ® PUC and Precipath ® PUC, Roche claims substantial equivalence to the currently marketed Roche Diagnostics Precinorm ® PUC and Precipath ® PUC (K041812).

Substantial Equivalence – Device comparison

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

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510(k) Summary, continued

Characteristic	Precinorm ® PUC / Precipath® PUC (Predicate device, K040264)	Precinorm ® PUC / Precipath® PUC (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	Liquid ready-for-use control based on a buffered aqueous solution. Concentrations of control components have been adjusted to represent normal and pathological ranges.	Same
Stability	Unopened Stable at 2-8°C until expiration date Opened: Stable at 2 to 8°C for 4 weeks	Same
Constituent Analytes with Assigned Values	Precinorm • Albumin • Creatinine • Total Protein Precipath • Albumin • Creatinine • Total Protein • Immunoglobulin A • Immunoglobulin M	Precinorm • Albumin • Creatinine • Total Protein • Immunoglobulin G Precipath • Albumin • Creatinine • Total Protein • Immunoglobulin A • Immunoglobulin M • Immunoglobulin G

Note:
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510(k) Summary, continued

Characteristic	Precinorm ® PUC / Precipath® PUC (Predicate device, K040264)	Precinorm ® PUC / Precipath® PUC (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	Liquid ready-for-use control based on a buffered aqueous solution. Concentrations of control components have been adjusted to represent normal and pathological ranges.	Same
Stability	Unopened Stable at 2-8°C until expiration date Opened: Stable at 2 to 8°C for 4 weeks	Same
Constituent Analytes with Assigned Values	Precinorm • Albumin • Creatinine • Total Protein Precipath • Albumin • Creatinine • Total Protein • Immunoglobulin A • Immunoglobulin M	Precinorm • Albumin • Creatinine • Total Protein • Immunoglobulin G Precipath • Albumin • Creatinine • Total Protein • Immunoglobulin A • Immunoglobulin M • Immunoglobulin G

DEPARTMENT OF HEALTH & HUMAN SERVICES

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JAN 31 2005

Re: k050026
Trade/Device Name: C.f.a.s (Calibrator for Automated Systems) Proteins in Urine/CSF (PUC)
Precinorm® Proteins in Urine/CSF (PUC) and Precipath ® PUC
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX, JJY
Dated: January 5, 2005
Received: January 6, 2005

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 (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,

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): K050026

Device Name: Precinorm ® Proteins in Urine/CSF (PUC) and Precipath ® PUC

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 ___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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050026

Indications for Use

510(k) Number (if known): K050026

Device Name: C.f.a.s. (Calibrator for Automated Systems) Proteins in Urine/CSF (PUC)

Indications For Use:

C.f.a.s. PUC is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers 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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

K050026