Premarket Notification [510(k)] Summary

MAR - 5 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K071779

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Date Prepared: 21st December 2007

Device Name:
The following calibrator is for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

CALIBRATOR:

Trade/Proprietary Name:	**ABX PENTRA Urine Cal**
Common or Usual Name:	Urine calibrator
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIT ; Calibrator, Secondary

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to the predicate device:

Submission device	Substantially equivalent Predicate device
ABX PENTRA Urine Cal	K050026

Description:

The calibrator included in this submission is for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Urine Cal** is a liquid calibrator based on a buffered aqueous solution, with chemical additives and materials of biological origin. The assigned values of the calibrator components are given in the enclosed annex, ensuring optimal calibration of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. This calibrator is provided in three vials of 1 ml.

Intended Use:

This calibrator is intended for use on the **ABX PENTRA 400** in association with the ABX Pentra Urinary Proteins CP reagent for the quantitative determination of total proteins in urine.

CALIBRATOR

ABX PENTRA Urine Cal:	
Analytes	Total Proteins in urine
Format	Liquid with chemical additives and materials of biological origin
Stability	Closed stability: 12 months at 2-8°C Open stability: 4 weeks at 2-8°C

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the device are not compromised, and that they met all acceptance criteria, demonstrating that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Horiba ABX
c/o Olivier Ducamp
Regulatory Affairs Manager
Parc Euromédecine
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MAR - 5 2008

Re: k071779
Trade/Device Name: ABX Pentra Urine Calibrator
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator, Multi-analyte mixture
Regulatory Class: Class II
Product Code: JIX
Dated: February 05, 2008
Received: February 08, 2008

Dear Mr. Ducamp:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

Indication for Use

510(k) Number (if known): K071779

Device Name: ABX PENTRA Urine Cal

Indication For Use:

The ABX PENTRA Urine Cal is a calibrator for use in the calibration of the quantitative method : ABX PENTRA Urinary Proteins CP on Horiba ABX PENTRA 400 clinical chemistry analyzer.

Prescription Use _X_____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071779