Premarket Notification [510(k)] Summary

AUG 24 2006

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 : ____**K060854**_____

Company: Horiba ABX
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE
Telephone: + (33) 4 67 14 73 20
Fax: + (33) 4 67 14 15 17

Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 10 July 2006

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA Cholesterol CP**
Common or Usual Name:	Cholesterol
Device Class	Class I
Classification Name:	§862.1175 : Cholesterol (Total) Test System
Product Code:	CHH ; Enzymatic Esterase-Oxidase, Cholesterol

Trade/Proprietary Name:	**ABX PENTRA HDL Direct CP**
Common or Usual Name:	HDL Cholesterol
Device Class	Class I
Classification Name:	§862.1475 : Lipoprotein Test System
Product Code:	LBS ; LDL/VLDL Precipitation, Cholesterol via Esterase-Oxidase, HDL

Trade/Proprietary Name:	**ABX PENTRA LDL Direct CP**
Common or Usual Name:	LDL Cholesterol
Device Class	Class I
Classification Name:	§862.1475 : Lipoprotein Test System
Product Code:	LBS ; LDL/VLDL Precipitation, Cholesterol via Esterase-Oxidase, HDL

Trade/Proprietary Name:	**ABX PENTRA Triglycerides CP**
Common or Usual Name:	Triglycerides
Device Class	Class I
Classification Name:	§862.1705 : Triglycerides Test System
Product Code:	CDT ; Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides

CALIBRATORS:

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

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

Trade/Proprietary Name:	**ABX PENTRA Multical** (K052007)
Common or Usual Name:	Multical
Device Class	Class II
Classification Name:	§862.1150 : Calibrator
Product Code:	JIX ; Calibrator, Multi-Analyte Mixture

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA N Control** (K052007)
Common or Usual Name:	N Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (Assayed)

Trade/Proprietary Name:	**ABX PENTRA P Control** (K052007)
Common or Usual Name:	P Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

CLEANING SOLUTIONS:

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem 99 CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem 99
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA Cholesterol CP	K941573
ABX PENTRA HDL Direct CP	K021316
ABX PENTRA LDL Direct CP	K971573
ABX PENTRA Triglycerides CP	K893973
ABX PENTRA HDL Cal	K021316
ABX PENTRA LDL Cal	K971573
ABX PENTRA Multical	K052007
ABX PENTRA N Control	K052007
ABX PENTRA P Control	K052007

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA Cholesterol CP** is an in vitro diagnostic assay for the quantitative determination of cholesterol in human serum and plasma based on an enzymatic photometric test (Trinder's reaction). The assay is composed of a 99 ml mono-reagent cassette. Reagent is a chemical solution with additives.

The **ABX PENTRA HDL Direct CP** is an in vitro diagnostic assay for the quantitative determination of High Density Lipoprotein Cholesterol (HDL-C) in human serum and plasma based on an enzymatic test, with accelerator selective detergent methodology. The assay is composed of a bi-reagent cassette, with 62 ml and 21 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA HDL Direct CP** is an in vitro diagnostic assay for the quantitative determination of Low Density Lipoprotein Cholesterol (LDL-C) in human serum and

plasma based on an enzymatic colorimetric test. It is composed of a bi-reagent cassette, with 28 ml and 10 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA Triglycerides CP** is an in vitro diagnostic assay for the quantitative determination of triglycerides in human serum and plasma based on an enzymatic colorimetric test. It is composed of a 99 ml mono-reagent cassette. Reagent is a chemical solution with additives.

The **ABX PENTRA HDL Cal** is a lyophilized calibrator prepared from human serum. It is used for the calibration of the HDL-C assay. The assigned value is given in the enclosed annex. This calibrator is provided in two vials of 1 ml.

The **ABX PENTRA LDL Cal** is a lyophilized calibrator prepared from human serum. It is used for the calibration of the LDL-C assay. The assigned value is given in the enclosed annex. This calibrator is provided in two vials of 1 ml.

The **ABX PENTRA Multical** is a lyophilized human serum calibrator 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 ten vials of 3 ml.

The **ABX PENTRA N Control** and **ABX PENTRA P Control** are quality control products consisting of lyophilized human serum with chemical additives and materials of biological origin added as required to obtain given component levels. The assigned values of the control components are given in the enclosed annexes, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each control is provided in ten vials of 5 ml.

The **ABX PENTRA Clean-Chem CP** and **ABX PENTRA Clean-Chem 99 CP** are ready-to-use chemical cleaning solutions for use on the ABX Pentra 400 system. They are respectively provided in mono-reagent 30 ml and 4 x 99 ml cassettes.

Intended Use :

All reagents in this submission are intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of their respective analytes : Cholesterol, HDL-C, LDL-C and Triglycerides using human serum and plasma.

The controls, calibrators and additional reagents are intended for use in association with the above reagents.

Discussion of Performance Data:

ABX PENTRA Cholesterol CP :	
Sample type	Serum & plasma
Detection limit	4 mg/dl
Accuracy and Precision	CV Total < 3.01%
Measuring range	2.55 mg/dl – 583.26 mg/dl
Upper linearity limit	580 mg/dl
Correlation (n=135)	Y = 0.95 x + 1.90 with a correlation coefficient $r^2 = 0.9943$.
Calibration stability	8 days
Reagent stability	closed stability: 24 months at 2-8°C on-board stability (refrigerated area): 48 days

ABX PENTRA HDL Direct CP :	
Sample type	Serum & plasma
Detection limit	1.16 mg/dl
Accuracy and Precision	CV Total < 3.52%
Measuring range	5.4 mg/dl – 151.9 mg/dl
Upper linearity limit	154.8 mg/dl
Correlation (n=121)	Y = 0.91 x + 1.98 with a correlation coefficient $r^2 = 0.9768$.
Calibration stability	14 days
Reagent stability	closed stability: 22 months at 2-8°C on-board stability (refrigerated area): 31 days

ABX PENTRA LDL Direct CP :	
Sample type	Serum & plasma
Detection limit	1.55 mg/dl
Accuracy and Precision	CV Total < 6.39%
Measuring range	1.35 mg/dl – 369.39 mg/dl
Upper linearity limit	387 mg/dl
Correlation (n=122)	Y = 0.96 x - 0.21 with a correlation coefficient $r^2 = 0.9963$.
Calibration stability	12 days
Reagent stability	closed stability: 18 months at 2-8°C on-board stability (refrigerated area): 97 days

ABX PENTRA Triglycerides CP :	
Sample type	Serum & plasma
Detection limit	7 mg/dl
Accuracy and Precision	CV Total < 2.83%
Measuring range	3.1 mg/dl – 1434 mg/dl
Upper linearity limit	1470 mg/dl, with an automatique post-dilution : 5580 mg/dl
Correlation (n=135)	Y = 0.99 x + 0.20 with a correlation coefficient $r^2 = 0.9994$.
Calibration stability	14 days
Reagent stability	closed stability: 16 months at 2-8°C on-board stability (refrigerated area): 48 days

CALIBRATORS

ABX PENTRA HDL Cal:	
Analytes	High Density Lipoprotein Cholesterol (HDL-C)
Format	Lyophilized preparation of human serum
Stability	Closed stability: 24 months at 2°C to 8°C Open stability: 14 days at 2°C to 8°C 4 weeks at -70°C

ABX PENTRA LDL Cal:	
Analytes	Low Density Lipoprotein Cholesterol (LDL-C)
Format	Lyophilized preparation of human serum
Stability	Closed stability: 24 months at 2°C to 8°C Open stability: 2 weeks at 2°C to 8°C

THIS PART IS LEFT INTENTIONALLY BLANK

ABX PENTRA Multical:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase*		
Amylase*		
Aspartate aminotransferase*		
Creatine kinase*		
GGT*		
Lactate Dehydrogenase*		
Lipase*		
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Cholesterol		√
Creatinine*		
Glucose HK	√	
Glucose PAP	√	
Iron*		
Lactic acid*		
Magnesium*		
Phosphorus*		
Total Protein*		
Triglycerides		√
Urea / Blood Urea Nitrogen*		
Uric acid*		

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 24 months at 2-8°C Open stability: Once opened, the calibrator components** are stable for : 8 hours at 15°C to 25°C 2 days at 2°C to 8°C 2 weeks at –25°C to –15°C **Exceptions Direct Bilirubin 3 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 6 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

CONTROLS

ABX PENTRA N Control:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase*		
Amylase*		
Aspartate aminotransferase*		
Creatine kinase*		
GGT*		
Lactate Dehydrogenase*		
Lipase*		
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Chloride	√	√
Cholesterol		√
HDL		√
LDL		√
Creatinine*		
Glucose HK	√	√
Glucose PAP	√	√
Iron*		
Lactic acid*		
Magnesium*		
Phosphorus*		
Potassium	√	√
Sodium	√	√
Total Protein*		
Triglycerides		√
Urea / Blood Urea Nitrogen*		
Uric acid*		

.../...

Format	Lyophilized human serum with chemical additives and materials of biological origin
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions

ABX PENTRA N Control:	
	Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C Total Bilirubin 8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

THIS PART IS LEFT INTENTIONALLY BLANK

ABX PENTRA P Control:		
Analytes	Already cleared (K052007)	Included in this submission
Alkaline phosphatase*		
Alanine aminotransferase*		
Amylase*		
Aspartate aminotransferase*		
Creatine kinase*		
GGT*		
Lactate Dehydrogenase*		
Lipase*		
Albumin*		
Direct Bilirubin*		
Total Bilirubin*		
Calcium*		
Chloride	√	√
Cholesterol		√
HDL		√
LDL		√
Creatinine*		
Glucose HK	√	√
Glucose PAP	√	√
Iron*		
Lactic acid*		
Magnesium*		
Phosphorus*		
Potassium	√	√
Sodium	√	√
Total Protein*		
Triglycerides		√
Urea / Blood Urea Nitrogen*		
Uric acid*		
Format	Lyophilized human serum with chemical additives and materials of biological origin	
Stability	Closed stability: 30 months at 2-8°C Open stability: Once opened, the control components** are stable for : 12 hours at 15°C to 25°C 5 days at 2°C to 8°C 1 month at –25°C to –15°C **Exceptions Direct Bilirubin 4 hours at 15°C to 25°C 8 hours at 2°C to 8°C 2 weeks at –25°C to –15°C .../... Total Bilirubin	

	8 hours at 15°C to 25°C 1 day at 2°C to 8°C 2 weeks at –25°C to –15°C

* Not cleared as of date of submission

CLEANING SOLUTIONS

ABX PENTRA Clean-Chem CP:	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 15 days

ABX PENTRA Clean-Chem 99 CP:	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 45 days

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Tim Lawton
Regulatory Affairs Manager
Horiba ABX
Parc Euromèdecine
Rue du Caducèe – BP 7290
34184 Montpellier cedex 4 - France

AUG 2 4 2006

Re: k060854
Trade/Device Name: Lipoproteins and associated calibrators and controls on ABX PENTRA 400 Clinical Chemistry Analyzer
Regulation Number: 21CFR§-862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, CHH, JJY, CDT, LBR, MRR
Dated: July 10, 2006
Received: July 14, 2006

Dear Mr. Lawton:

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,

Alberto Gutierrez, Ph.D.
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): k060854

Device Name: Lipoproteins and associated calibrators and controls on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Cholesterol CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of cholesterol in human serum and plasma based on an enzymatic photometric test (Trinder's reaction).

ABX PENTRA HDL Direct CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of High Density Lipoprotein Cholesterol (HDL-C) in human serum and plasma based on an enzymatic assay with accelerator selective detergent methodology.

ABX PENTRA LDL Direct CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of Low Density Lipoprotein Cholesterol (LDL-C) in human serum and plasma based on an enzymatic colorimetric assay.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

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

K060854

Indications for Use

510(k) Number (if known): k060854

Device Name: Lipoproteins and associated calibrators and controls on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

ABX PENTRA Triglycerides CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of triglycerides in human serum and plasma based on an enzymatic colorimetric assay.
Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

The ABX PENTRA HDL Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA HDL Direct CP method on Horiba ABX clinical chemistry analyzers.

The ABX PENTRA LDL Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA LDL Direct CP method on Horiba ABX clinical chemistry analyzers.

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

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060854