

## Premarket Notification [510(k)] Summary

AUG 16 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 : K060325

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

Date Prepared: 06<sup>th</sup> February 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 Bilirubin, Direct CP**  
Common or Usual Name: Direct Bilirubin  
Device Class: Class II  
Classification Name: §862.1110 : Bilirubin (Total or Direct) Test System  
Product Code: CIG ; Diazo Colorimetry, Bilirubin

Trade/Proprietary Name: **ABX PENTRA Bilirubin, Total CP**  
Common or Usual Name: Total Bilirubin  
Device Class: Class II  
Classification Name: §862.1110 : Bilirubin (Total or Direct) Test System  
Product Code: CIG ; Diazo Colorimetry, Bilirubin

#### 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 and unassayed)  
Product Code: JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

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 and unassayed)  
 Product Code: JJY ; Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

**CALIBRATORS:**

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

**Substantial Equivalence:**

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

<b>Submission device</b>	<b>Substantially equivalent Predicate device</b>
ABX PENTRA Bilirubin, Direct CP	K910593
ABX PENTRA Bilirubin, Total CP	K910591

**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 400** offers both Closed and Open channels for a multitude of parameters (clinical chemistry, DAT, TDM, plasma protein, hemostasis, optional ISE module).

All reagents described in this submission are for the quantitative in-vitro determination of their respective parameters.

**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 (Direct Bilirubin, Total Bilirubin) using human serum and plasma.  
 The controls and calibrators are intended for use in association with the above reagents.

## Discussion of Performance Data:

<b>ABX PENTRA Bilirubin, Direct CP :</b>	
Sample type	Serum & plasma
Detection limit	0.04 mg/dl
Accuracy and Precision	CV Total < 4.26%
Measuring range	0.04 mg/dl – 6.79 mg/dl Automatic post-dilution : 33.90 mg/dl
Correlation (n=110)	$Y = 1.09 x + 0.03$ with a correlation coefficient $r^2 = 0.9974$ .
Calibration stability	10 days
Reagent stability	closed stability: 18 months at 2-8°C on-board stability (refrigerated area): 25 days

<b>ABX PENTRA Bilirubin, Total CP :</b>	
Sample type	Serum & plasma
Detection limit	0.20 mg/dl
Accuracy and Precision	CV Total < 3.35%
Measuring range	0.20 mg/dl – 69.38 mg/dl Automatic post-dilution : 346.90 mg/dl
Correlation (n=106)	$Y = 1.00 x - 0.13$ with a correlation coefficient $r^2 = 0.9961$ .
Calibration stability	10 days
Reagent stability	closed stability: 18 months at 2-8°C on-board stability (refrigerated area): 25 days

## CALIBRATORS

<b>ABX PENTRA Multical:</b>	
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

	<p><b>*Exceptions</b></p> <p><b>Direct Bilirubin</b></p> <p>3 hours at 15°C to 25°C  8 hours at 2°C to 8°C  2 weeks at -25°C to -15°C</p> <p><b>Total Bilirubin</b></p> <p>6 hours at 15°C to 25°C  1 day at 2°C to 8°C  2 weeks at -25°C to -15°C</p>
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## CONTROLS

<b>ABX PENTRA N Control:</b>	
Stability	<p>Closed stability: 30 months at 2-8°C</p> <p>Open stability:</p> <p>Once opened, the control components* are stable for :</p> <p>12 hours at 15°C to 25°C  5 days at 2°C to 8°C  1 month at -25°C to -15°C</p> <p><b>*Exceptions</b></p> <p><b>Direct Bilirubin</b></p> <p>4 hours at 15°C to 25°C  8 hours at 2°C to 8°C  2 weeks at -25°C to -15°C</p> <p><b>Total Bilirubin</b></p> <p>8 hours at 15°C to 25°C  1 day at 2°C to 8°C  2 weeks at -25°C to -15°C</p>

<b>ABX PENTRA P Control:</b>	
Stability	<p>Closed stability: 30 months at 2-8°C</p> <p>Open stability:</p> <p>Once opened, the control components* are stable for :</p> <p>12 hours at 15°C to 25°C  5 days at 2°C to 8°C  1 month at -25°C to -15°C</p> <p><b>*Exceptions</b></p> <p><b>Direct Bilirubin</b></p> <p>4 hours at 15°C to 25°C  8 hours at 2°C to 8°C  2 weeks at -25°C to -15°C</p>

	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
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**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 Manger  
Horiba ABX  
Parc Euromèdecine  
Rue du Caducèe-BP 7290  
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AUG 16 2006

Re: k060325  
Trade/Device Name: Bilirubin on ABX PENTRA 400 Clinical Chemistry Analyzer  
ABX PENTRA Multical  
ABX PENTRA N Control  
ABX PENTRA P Control  
Regulation Number: 21 CFR§862.1110  
Regulation Name: Bilirubin (total and direct) test system  
Regulatory Class: Class II  
Product Code: CIG, JJY, JIX,  
Dated: July 5, 2006  
Received: July 7, 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.

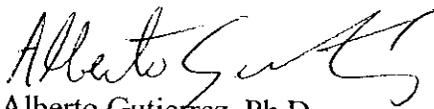
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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): k060325

Device Name: Bilirubin on ABX PENTRA 400 Clinical Chemistry Analyzer

### Indications For Use:

ABX PENTRA Bilirubin, Direct CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of direct bilirubin in human serum and plasma based on a photometric test using 2,4-dichloroaniline (DCA) for use on ABX PENTRA 400 Clinical Chemistry Analyzer.

ABX PENTRA Bilirubin, Total CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of total bilirubin in human serum and plasma based on a photometric test using 2,4-dichloroaniline (DCA) and detergents for use on ABX PENTRA 400 Clinical Chemistry Analyzer.

Measurements of the levels of bilirubin (direct or total), an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

[Signature]  
Division Sign-Off

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Office of In Vitro Diagnostic Device  
Regulation and Safety

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## Indications for Use

510(k) Number (if known): K060325

Device Name: ABX PENTRA Multical

Indications For Use:

The ABX PENTRA Multical is a calibrator for use in the calibration of quantitative Horiba ABX methods on Horiba ABX clinical chemistry analyzers.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

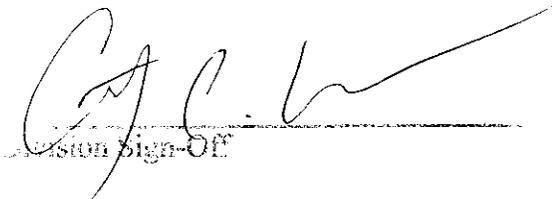
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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## Indications for Use

510(k) Number (if known): K060325

Device Name: ABX PENTRA N Control

Indications For Use:

The ABX PENTRA N Control is for use in quality control by monitoring accuracy and precision.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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## Indications for Use

510(k) Number (if known): K060325

Device Name: ABX PENTRA P Control

Indications For Use:

The ABX PENTRA P Control is for use in quality control by monitoring accuracy and precision.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

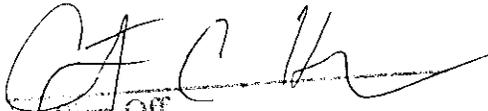
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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