JUL 1 1 2014

510(k) Summary
ABX Pentra Micro ALB Control L/H

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: k133676

1.0 Submitter

Horiba ABX SAS
Parc Euromédecine
Rue du Caducée – BP 7290
34184 Montpellier cedex 4
FRANCE
Telephone: + (33) 4 67 14 18 43
Fax: + (33) 4 67 14 15 17

Contact Persons

Caroline Ferrer, Regulatory Affairs Manager (caroline.ferrer@horiba.com)
Christelle Calvo, Regulatory Affairs Support (christelle.calvo@horiba.com)

Date of Summary Preparation

July 08, 2014

2.0 Device Identification

The following control is for use in conjunction with the ABX PENTRA 400 instrument, cleared to market under k052007.

Trade/Proprietary Name:	ABX Pentra Micro ALB Control L/H
Model Number:	A11A01967
Common or Usual Name:	Micro ALB Control
Device Class	Class I
Classification Panel:	Clinical Chemistry
Regulation:	21 CFR § 862.1660 Quality control material (assayed and unassayed)
Product Code:	JJY; Multi-Analyte Controls, All Kinds (Assayed)

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Microalbumin Control
Bio-Rad Laboratories
Irvine, California
510 (k) Number: k072835

4.0 Description of Device

The control included in this submission is for use on the **ABX PENTRA 400** (K052007) which is discrete photometric benchtop clinical chemistry analyzer. There is no any modifications to the cleared instrument for this particular assay.

The **ABX Pentra Micro ALB Control L/H** is a two-level (Low and High) quality control consisting of liquid solutions prepared from human urine with added chemicals, constituents of human origin, stabilizers and preservatives. The assigned values and precise confidence interval are given in an enclosed annex, ensuring control of the appropriate HORIBA ABX SAS methods on the HORIBA clinical chemistry analyzer. Each control level is provided in one vial of 10 ml.

5.0 Value Assignment

Assigned values were determined by calculating the mean value obtained from multiple determinations. The concentration of the constituent(s) is lot specific. Assigned values and the corresponding ±3SD confidence ranges are indicated in a specific annex. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended use

ABX Pentra Micro ALB Control L/H is a quality control used to monitor the performance of ABX Pentra Micro ALBUMIN CP determination by immunoturbidimetry.

7.0 Comparison of the new device with the Predicate Device

The new ABX Pentra Micro ALB Control L/H claims substantial equivalence to the Liquichek Microalbumin Control currently in commercial distribution (k072835).
Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Differencies and Similarities between predicate device and new device

	Predicate device (k072835):	**New Device :**
Device Name	**Liquichek Microalbumin Control**	**ABX Pentra Micro ALB Control L/H**
Differences		
Commercialized by	Bio-Rad Laboratories	HORIBA ABX SAS
Indication for Use :	Liquichek Microalbumin Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	ABX Pentra Micro ALB Control L/H is a quality control used to monitor the performance of ABX Pentra Micro ALBUMIN CP determination by immunoturbidimetry.
Analytes	Microalbumin and creatinine	Microalbumin
Similarities		
Produced by	Bio-Rad Laboratories	Same
Shelf Life	2-8°C until expiration date	Same
Open stability	90 days at 2 to 8°C	Same
Format / Packaging	In liquid form in 10mL vials for both level 1 and level 2	Same
Matrix	Human urine with added constituents of human origin, chemicals, preservatives and stabilizers.	Same

8.0 Statement of Supporting Data

Real time stability studies were conducted to establish the shelf life and open vial stability claims. Acceptance criteria were met to support the product claims as follows:
Shelf Life: 24 months at 2 to 8°C.
Open vial stability: 90 days at 2 to 8°C.

9.0 Conclusion

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 device is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

HORIBA ABX SAS
C/O CAROLINE FERRER
PARC EUROMEDECINE
RUE DU CADUCEE
MONTPELLIER 34184 FRANCE

Re: K133676
Trade/Device Name: ABX Pentra Micro ALB Control L/H
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: June 9, 2014
Received: June 13, 2014

Dear Ms. Caroline Ferrer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133676

Device Name
ABX Pentra Micro ALB Control L/H

Indications for Use *(Describe)*
ABX Pentra Micro ALB Control L/H is a quality control used to monitor the performance of ABX Pentra Micro ALBUMIN CP determination by immunoturbidimetry.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."