JUN 1 - 2005

Premarket Notification [510(k)] Summary

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 : K050721

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

Date Prepared: 14th March 2005

Device Name:

Trade/Proprietary Name:	**ABX ERYTROL**
Common or Usual Name:	Hematology Quality Control Mixture counter
Device Class	Class II : Hematology Device
Classification Name:	AutoHematology Quality Control Mixture
Product Code:	JPK

Substantial Equivalence:
The ABX Erytrol is substantially equivalent to another hematology blood control of the PENTRA 5D Hematology control approved by R& D Systems Inc under the submission K003534.

Description:
The ABX Erytrol is an in-vitro diagnostic blood control composed of human erythrocytes & mammalian leukocytes in a plasma-like fluid with preservatives.
The ABX Erytrol is composed of stable materials that provide a means of monitoring the performance of ABX hematology analyzers offering the nucleated red blood cell count (NRBC) parameter.

Intended Use :
ABX Erytrol is a tri-level control design for use in monitoring the accuracy and precision of the HoribaABX hematology blood cell counters for the nucleated red blood cell count (NRBC parameter). Refer to the assay table for specific instrument models.

Determination of substantial equivalence :
ABX Erytrol has an intended use that is identical to the predicate device for use in monitoring the accuracy and precision. The technologies of the two devices are identical.

Discussion of Performance Data:
ABX Erytrol underwent non clinical testing of 3 validation lots centered on the performance attributes of stability and precision, passing the acceptance criteria of remaining within the assay range over the life of the product. ABX Erytrol also demonstrated precision as indicated by the small standard deviations and % CV obtained during testing.

Expiration dating has been established at 60 days in the customers hands (closed vial) and 10 days, or 12 entries, open vial when stored at 2-8°C and handled according to instructions for use.

All non clinical tests show appropriate levels of safety and effectiveness for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 - 2005

Mr. Tim Lawton
Regulatory Affairs Manager
HORIBA ABX Diagnostics
Parc Euromedecine
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34184 Montpellier cedex 4
FRANCE

Re: k050721
Trade/Device Name: ABX ERYTROL
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology Quality Control Mixture
Regulatory Class: II
Product Code: JPK
Dated: April 29, 2005
Received: May 9, 2005

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,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050721

Device Name: ABX ERYTROL

Indications For Use:

ABX Erytrol is a tri-level control designed for use in monitoring the accuracy and precision of the HoribaABX hematology blood cell counters for NRBC parameter. Refer to the assay table for specific instrument models.

Prescription Use __V_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety