Summary of Safety and Effectiveness

APR 0 9 2003

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: K030801

Submitter's Name and Address

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591
Establishment Registration Number: 2432235

Contact Person: Andres Holle
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Contract Manufacturer

Randox Laboratories
55 Diamond Road
Crumlin, County Antrim, UK
Establishment Registration: 8020890

Device Name:	Special Chemistry Control
Proprietary/Trade Name	Bayer ADVIA 1650 Special Chemistry Control
Common Name:	Quality Control Material
Classification Name:	Enzyme Controls (assayed and unassayed)
Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	Chemistry (75)
Product Code:	JJY

Predicate Device:

Bayer Special Chemistry Control
Premarket Notification Number: K023840

Device Description:

The Bayer Special Chemistry Controls are two separate levels of quality control material prepared from human serum with non-serum constituents added.

All the analytes currently in the calibrator and control material are:
Acid Phosphatase
Lactate
Pancreatic Amylase
Lipase

The intention of this submission is to add the assigned values to the labeling claims for:
Pancreatic Amylase
Lipase

Intended Use:

The Special Chemistry Controls are assayed control materials for in vitro diagnostic use to monitor the precision and accuracy of certain chemistry test procedures for the ADVIA 1650 Chemistry analyzer.

Substantial Equivalence:

The Special Chemistry Controls are identical in intended use, storage and handling, stability, source material (human serum), and instructions for use as the previously cleared Special Chemistry Controls. The only difference in these controls is the addition of the assigned values in the labeling of two new analytes: Pancreatic Amylase and Lipase.

As with the predicate device, the control materials are lyophilized and require reconstitution with 5.0 mL distilled water. These controls are only for use on the Bayer ADVIA 1650 Chemistry Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 0 9 2003

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591

Re: k030801
Trade/Device Name: Special Chemistry Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I
Product Code: JJY
Dated: March 10, 2003
Received: March 13, 2003

Dear Mr. Holle:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030801

Device Name: Special Chemistry Control

Indications for Use:

For in vitro diagnostic use in the control of ADVIA 1650 Chemistry system for certain chemistry methods.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030801