OCT 3 - 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ADVIA® Chemistry Microalbumin Controls

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052242

1. Submitter's name, address and telephone number:

Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
A subsidiary of Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591
TEL: 914-524-3494
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2. Name of the device:

a) Classification Names: Quality Control Material, §862.1660
Classification: Class I
Product Code: 75 JJW

b) Common name: Assayed Quality Control Material

c) Proprietary name: ADVIA® Chemistry Microalbumin Controls

d) The device:

Product Name	Part Number
ADVIA® Chemistry Microalbumin Controls	02185464

e) Contract Manufacturing Site:
Randox Laboratories, Inc.
55 Diamond Road
Crumlin, Antrim Country, UK

3. Predicate Device:

Product Name	Part Numbers
Urine Controls	AU2352, AU2353

Contract Manufacturing Site:
Randox Laboratories, Inc.
55 Diamond Road
Crumlin, Antrim Country, UK

510(k) Number: K043266

4. Description of the device:

The ADVIA® Chemistry Microalbumin Controls is a human urine based solution containing various constituents.

5. Statement of Intended Use

ADVIA® Chemistry Microalbumin Controls is intended for in vitro diagnostic use in the control of ADVIA® Chemistry systems for the Microalbumin method.

6. Product Performance

The stability of the ADVIA® Chemistry Microalbumin Control values have been validated according to established procedures at the manufacturing site. The performance of the control is similar to other products in commercial distribution intended for similar use.

7. Substantial Equivalence:

Feature	Predicate Urine Controls (K043266)	ADVIA® Chemistry Microalbumin Control
Format	Lyophilized mixture of human urine base to which appropriate constituents have been added to achieve specific concentrations.	Same
Constituent Analytes	• Multiple analytes	• Microalbumin values only
Stability	• Reconstituted urine controls are stable for 8 hours at 25°C and 5 days at 4°C if kept capped in original container and free from contamination or 14 days at -20°C.	• Reconstituted, capped and stored at 2-8°C stable for 28 days • 24 month shelf life
Levels	• Two levels	Same

Andres Holle
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date 8/12/2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 3 - 2005

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

Re: k052242
Trade/Device Name: ADVIA® Chemistry Microalbumin Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: August 12, 2005
Received: August 18, 2005

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 (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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K052242

Device Name: ADVIA® Chemistry Microalbumin Control

Indications For Use:

The *ADVIA Chemistry Microalbumin Control* is intended for *in vitro* diagnostic use in the control of the ADVIA® Chemistry systems for the Microalbumin method.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Division) K052242