JUL - 6 2006

Summary of Safety and Effectiveness

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: k061137

Submitter's Name and Address

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

Contact Person: Andres Holle
Telephone: 914-524-3494
Fax: 914-524-2500
e-mail: andres.holle.b@bayer.com

Contract Manufacturer

Fisher Diagnostics
8365 Valley Pike
Middletown, VA 22645-0307
Establishment Registration: 1181121

Device Name:	ADVIA® IMS cPSA Control
Proprietary/Trade Name:	ADVIA® IMS cPSA Control
Common Name:	Assayed Quality Control Material
Classification Name:	Assayed Quality Control Material
Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	Chemistry (75)
Product Code:	JJY

Predicate Device:

Bayer Special Chemistry Controls
Premarket Notification Number: K033379

Device Description:

The Bayer ADVIA® IMS cPSA Controls
are bovine serum based with non-serum constituents added.

The analytes currently in the control material are:
cPSA

Intended Use:

For in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer Immuno1® systems.

Substantial Equivalence:

The ADVIA® IMS cPSA Controls are substantially equivalent in intended use, storage and handling, stability, source material, and instructions for use as the previously cleared Bayer Special Chemistry Controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 6 2006

Bayer Healthcare, LLC
c/o Mr. Andres Holle
Manager, Regulatory Affairs
511 Benedict Ave.
Tarrytown, NY 10591-5097

Re: k061137
Trade/Device Name: ADVIA® IMS cPSA Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: April 17, 2006
Received: April 25, 2006

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.

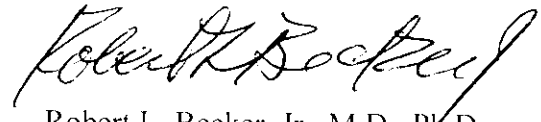
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Part 801); 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.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known):___K061137_____

Device Name: ADVIA® IMS cPSA Control

Indications for Use:

For in vitro diagnostic use to monitor the precision and the accuracy of the assayed, quantitative complexed PSA assays on the ADVIA® IMS and Bayer Immuno1® systems.

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

510(k) K061137