

K982802

SEP 22 1998

**510(k) Summary of Safety and Effectiveness**

The following information provides data supporting a substantially equivalent determination between the ADVIA 60 Hematology System and the ABX MICROS Hematology System for CBC and WBC differential parameters.

**Intended Use**

The ADVIA 60 Hematology System is a quantitative, automated hematology analyzer that provides a leukocyte differential count for *In Vitro* diagnostic use in clinical laboratories.

**Device Description**

The ADVIA 60 Hematology System consists of an analytical module that aspirates, dilutes, and analyzes whole blood samples along with a printer that optionally generates reports based on the instrument results.

The ADVIA 60 Hematology System reports the following hematological parameters:

White Blood Cell Parameters

WBC - white blood cell count

GRA - granulocyte count (percentage and absolute counts)

LYM - lymphocyte count (percentage and absolute counts)

MON - mononuclear count (percentage and absolute counts)

Red Blood Cell Parameters

RBC - red blood cell count

Hct - hematocrit

MCV - mean corpuscular volume

RDW - red cell volume distribution width

Hemoglobin Parameters

Hgb - hemoglobin concentration

MCH - mean corpuscular hemoglobin

MCHC - mean corpuscular hemoglobin concentration

Platelet Parameters

Plt - platelet count

MPV - mean platelet volume

**Principles of Operation**

The principles of operation of the ADVIA 60 Hematology System are similar to those of the ABX MICROS Hematology System.

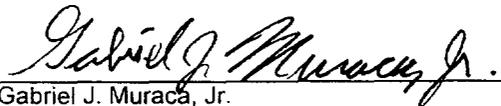
The RBC/WBC/Plt parameters are counted based on impedance variation generated by the passage of cells through a calibrated micro-aperture.

The hemoglobin parameters are based on a modification of the manual cyanmethemoglobin method developed by the International Committee for Standardization in Hematology.

The WBC differential parameters are derived through a volumetric study of leukocytes after the use of a diluent and lysing reagent.

**Conclusion**

The test results included in this submission demonstrate that the ADVIA 60 Hematology System and the ABX MICROS Hematology System have equivalent accuracy, precision, linearity, and carryover.



Gabriel J. Muraca, Jr.  
Manager Regulatory Affairs  
Bayer Corporation  
511 Benedict Avenue  
Tarrytown, New York 10591-5097



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Gabriel J. Muraca, Jr.  
Manager Regulatory Affairs  
Bayer Corporation  
511 Benedict Avenue  
Tarrytown, New York 10591-5097

Re: K982802  
Trade Name: Bayer ADVIA® 60 Hematology System  
Regulatory Class: II  
Product Code: GKZ  
Dated: July 31, 1998  
Received: August 10, 1998

Dear Mr. Muraca:

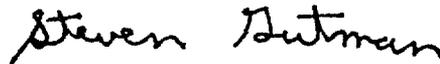
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K987802

Device Name: **Bayer ADVIA® 60 Hematology System**

Indications For Use:

The **Bayer ADVIA 60** is an automated in vitro diagnostic hematology analyzer capable of determining the following eighteen (18) hematological parameters:

white blood cells (leukocytes)	WBC
red blood cells (erythrocytes)	RBC
hemoglobin	HGB
hematocrit	HCT
mean corpuscular volume	MCV
mean corpuscular hemoglobin	MCH
mean corpuscular hemoglobin concentration	MCHC
red blood cell distribution width	RDW
platelets	PLT
mean platelet volume	MPV
lymphocyte (number)	#LYM
lymphocyte (percent of WBC)	%LYM
monocyte (number)	#MON
monocyte (percent of WBC)	%MON
granulocyte (number)	#GRA
granulocyte (percent of WBC)	%GRA

The **ADVIA 60** Hematology Analyzer can be programmed to printout any of the following groups of parameters:

- 16 parameters
- 8 parameters (WBC (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, and PLT)
- 5 parameters (WBC, RBC, MPV, HGB, HCT)

Only the eight (8) and sixteen (16) parameter printout will be made available for diagnostic use in the United States.

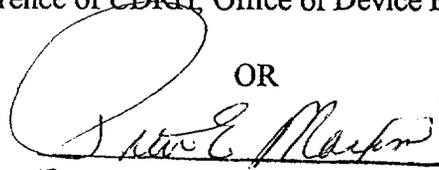
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Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use



Optional Format 1-2-96)

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