

## 510(k) Summary of Safety and Effectiveness

The following information provides data supporting a substantially equivalent determination between the ADVIA 120 Hematology System and the Technicon H-3 RTC for the CBC, WBC differential, and reticulocyte parameters.

### Intended Use

The ADVIA 120 Hematology System is a quantitative, automated hematology analyzer that provides a leukocyte differential count and reticulocyte analysis for *In Vitro* diagnostic use in clinical laboratories.

### Device Description

The ADVIA 120 Hematology System consists of the following: An analytical module that aspirates, dilutes, and analyzes whole blood samples. An autosampler that automatically mixes, identifies, and presents samples for processing. A computer workstation that controls the instrument, provides the primary user interface with the instrument, and manages the data produced by the instrument. A printer that optionally generates reports based on the instrument results.

The ADVIA 120 Hematology System reports the following hematological parameters:

#### White Blood Cell Parameters

WBC - white blood cell count

Neut - neutrophil count (percentage and absolute counts)

Lymph - lymphocyte count (percentage and absolute counts)

Mono - monocyte count (percentage and absolute counts)

Eos - eosinophil count (percentage and absolute counts)

Baso - basophil count (percentage and absolute counts)

LUC - large unstained cell 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

CHCM - hemoglobin concentration mean

HDW - hemoglobin concentration 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

Reticulocyte Count

retic - reticulocyte count (percentage and absolute counts)

MCVg - mean corpuscular volume of all gated red cells

MCVr - mean corpuscular volume of reticulocytes

CHCMg - hemoglobin concentration mean of all gated red cells

CHCMr - hemoglobin concentration mean of reticulocytes

CHg - mean hemoglobin content of all gated red cells

CHr - mean hemoglobin content of reticulocytes

**Principles of Operation**

The principles of operation of the ADVIA 120 Hematology System are similar to those of the H-3 RTC.

The WBC parameters are derived through a combination of laser light scatter, as well as light scatter and absorption from a tungsten light source based on cellular peroxidase activity.

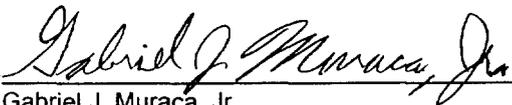
The RBC and platelet parameters are derived through laser light scatter and refractive index.

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

The reticulocyte parameters are derived through a combination of laser light scatter and absorption of a nucleic acid dye.

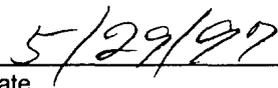
**Conclusion**

The test results included in this submission demonstrate that the ADVIA 120 Hematology System and the H-3 RTC 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





Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 29 1997

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

Re: K971998  
ADIVA™ 120 Hematology System  
Regulatory Class: II  
Product Code: GKL, GKZ  
Dated: July 23, 1997  
Received: July 28, 1997

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 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 (Premarket 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 premarket 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.

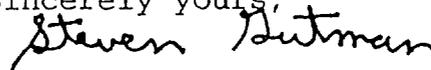
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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): \_\_\_\_\_

Device Name: ADVIA 120 Hematology System

Indications For Use:

The ADVIA 120 Hematology System is a quantitative, automated hematology analyzer that provides a leukocyte differential count and reticulocyte analysis for *in vitro* diagnostic use in clinical laboratories.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

1911998

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)