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.

5/29/97
Date

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511Benedict Avenue
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 29 1997

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
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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.

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 Gutman

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991898

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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