K022668

510(k) Summary of Safety and Effectiveness

OCT 15 2002

The following information provides data supporting a substantially equivalent determination between the ADVIA 120 cellular Hgb method (Hgb_{Cell}) and the ADVIA 120 Hgb_{Total} predicate method (K971998).

Intended Use

The ADVIA 120 Hgb_{Cell} parameter is intended to provide an *in vitro* diagnostic, quantitative measurement of hemoglobin concentration in a sample of whole blood.

Device Description

Cellular hemoglobin is currently a "laboratory use only" parameter on the ADVIA 120 system. There are no changes to software, reagents, calibrators or controls necessary to derive the cellular hemoglobin parameter.

Principles of Operation

The ADVIA 120 cellular hemoglobin method is derived from the RBC/Plt channel of the system. The RBC/Plt channel uses optical light scattering to derive RBC cell volume and cell hemoglobin concentration on a cell-by-by cell basis. The parameters MCV (mean corpuscular volume) and CHCM (corpuscular hemoglobin concentration mean) are then calculated as the mean of the volume and hemoglobin concentration histograms respectively, along with an RBC count. These parameters have previously received 510(k) clearance in K971998. The cellular hemoglobin concentration is then calculated as the product of the RBC count, the MCV, and CHCM, then scaled by a factor of 1/1000 to obtain units of grams per dL of whole blood.

Similarities and Differences between the ADVIA 120 Cellular Hgb Method and the ADVIA 120 Hgb Predicate Method (K971998)

The following table provides similarities and differences between the ADVIA 120 cellular Hgb Method and the ADVIA 120 cyanide containing predicate method.

Similarities/Differences	Characteristic	ADVIA 120 Hgb Method	ADVIA 120 Cellular Hgb
Similarities	Intended Use	To provide a quantitative measurement of hemoglobin concentration in whole blood.	Same as predicate method.
	Accuracy	As specified in product labeling.	Equivalent to predicate method.
	Precision	As specified in product labeling.	Equivalent to predicate method.
	Linearity	As specified in product labeling.	Equivalent to predicate method.
	Carryover	As specified in product labeling.	Equivalent to predicate method.
Differences	Reagent	ADVIA 120 HGB	ADVIA 120 RBC/PLT
	Method Principle	Colorimetric method	Laser optical method
	Sample stability	72 hours for samples stored at room temperature	24 hours for samples stored at room temperature

Conclusion

The test results included in this submission demonstrate that the ADVIA 120 cellular Hgb Method has equivalent accuracy, precision, linearity, and carryover substantially equivalent to the ADVIA 120 predicate method.

Date 8/09/02

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth T. Edds, Ph.D.
Regulatory Affairs Manager
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, New York 10591-5097

OCT 1 5 2002

Re: k022668
Trade/Device Name: Bayer ADVIA 120 Cellular Hemoglobin Parameter
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 12, 2002
Received: August 12, 2002

Dear Dr. Edds:

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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/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:

Device Name: Bayer ADVIA 120 Hematology analyzer

Indications for Use:
The ADVIA™ 120 Hematology System Complete Blood Count (CBC) method is intended to quantitatively measure the following hematological parameters:
White Blood Cell count (WBC)
Red Blood Cell count (RBC)
Total Hemoglobin concentration (HGB_{Total})
Cellular Hemoglobin concentration (HGB_{Cell})
Hematocrit (HCT)
Mean Corpuscular Volume (MCV)
Mean Corpuscular Hemoglobin (MCH)
Mean Corpuscular Hemoglobin Concentration (MCHC)
Corpuscular Hemoglobin Concentration Mean (CHCM)
Cellular Hemoglobin Content (CH)
Red Cell Volume Distribution Width (RDW)
Hemoglobin Concentration Distribution Width (HDW)
Platelet Count (PLT)
Mean Platelet Volume (MPV)

The difference between HGB_{Total} and HGB_{Cell} can be used to discriminate between cell-associated hemoglobin and cell-free hemoglobin as found in hemoglobin-based blood substitutes.

(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 K022668

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)