K971130

510(k) Summary of Safety and Effectiveness

Sysmex Corporation of America
Gilmer Road 6699 RFD
Long Grove, IL 60047-9596
(847)726-3662
Fax: (847)726-3505
Attention: Cathy Trester
Date Prepared: May 5, 1997

AUG 26 1997

Sysmex™ IRF parameter (MFR+HFR) on R-1000, R-3000, RAM-1 analyzers, Trade name and Common name

The Sysmex™ IRF parameter is substantially equivalent to the reticulocyte count, and shows agreement to the WBC count as predictive indicators of bone marrow suppression and recovery.
The IRF parameter is obtained from the Sysmex R-1000(Premarket Notification K894539) R-3000 (Premarket Notification K912494) or SE/RAM-1(Premarket Notification K964375).
The Sysmex™ R-3000, R-1000 and SE/RAM-1 are classified as Class II devices. The IRF parameter is classified as a Class III device.

Intended Use

The IRF is a clinical parameter obtained from the Sysmex™ R-Series automated reticulocyte analyzers. It is intended for in-vitro use in clinical laboratories. Its clinical use is to monitor bone marrow suppression and recovery in terms of erythropoiesis in situations of previous cancer chemotherapeutic bone marrow suppression and bone marrow transplantation. Qualified laboratory personnel are responsible for review of all abnormal results.

Device Description and Principles

The R-1000, R-3000 and RAM-1 are table-top analyzer systems for automated reticulocyte counting.
These instruments are dedicated flow cytometers which dilute and stain whole blood with a fluorescent dye (Auromine-O), then count and measure fluorescence and scatter of stained blood cells.
The fluorescence intensity is measured, and the analyzer identifies the reticulocytes based on fluorescence and scatter. The fluorescent intensity of the reticulocytes is displayed on the analyzer as a scattergram, and this display is separated into three regions: Low Fluorescence Intensity (LFR), Middle Fluorescence Intensity (MFR), and High Fluorescence Intensity (HFR). These regions are reported as a ratio or percentage(sum = 100%), in addition to the analyzer's reporting total reticulocyte count and RBC count. The IRF parameter is determined by the sum of the MFR (Middle Fluorescence Ratio) and HFR (High Fluorescence Ratio) {MFR+HFR=IRF}.

Comparison to Predicate Methodology and Clinical Data

In the area of assessment of bone marrow production, the predicate methodology is use of the white blood cell count (WBC), the absolute neutrophil count (ANC), or the reticulocyte count. The Immature Reticulocyte Fraction is similar to WBC and ANC, and similar or better than reticulocyte count as a monitor for bone marrow production. Clinical studies have been performed which support this claim for patients receiving myeloablative

chemotherapy. In addition, several clinical studies have been published which support this claim for patients having undergone bone marrow transplantation.

Conclusion

The Sysmex™ Immature Reticulocyte Fraction (IRF) parameter provided by the R-Series reticulocyte analyzers has been shown to be a parameter of predictive value for bone marrow suppression and recovery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Catherine M. Trester, M.T. (ASCP)
Clinical and Regulatory Affairs
SYSMEX™ Corporation
Gilmer Road, 6699 RFD
Long Grove, Illinois 60047-9596

AUG 26 1997

Re: K971736/S1
Trade Name: Sysmex™ Immature Reticulocyte Fraction (IRF) Parameter
Regulatory Class: III
Product Code: GKZ
Dated: July 16, 1997
Received: July 18, 1997

Dear Ms. Trester:

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 requirement, 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 at (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): K971736

Device Name: Immature Reticulocyte Fraction on R-Series Analyzers

Indications For Use:

The IRF parameter of the R-Series analyzers is intended for in-vitro use in clinical laboratories. Its clinical use is to monitor bone marrow suppression and recovery in terms of erythropoiesis in situations of previous cancer chemotherapeutic bone marrow suppression and bone marrow transplantation. Qualified laboratory personnel are responsible for review of all abnormal results.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

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

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

(Optional Format 1-2-96)