

MAR 11 2008

K953598

ATTACHMENT B
510(K) SUMMARY

**SERONO DIAGNOSTICS, INC.'S SYSTEM 9100+ PLUS
AUTOMATED HEMATOLOGY ANALYZERS**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Serono Diagnostics, Inc.
100 Cascade Drive
Allentown, Pennsylvania 18103

Phone: 610-264-2800
Facsimile: 610-266-4361

Contact Person: Laurence A. Potter
Serono Diagnostics, Inc.
Phone: 610-266-4315
Facsimile: 610-266-4361

Howard M. Holstein, Esq.
Regulatory Counsel for Serono Diagnostics, Inc.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109
Phone: 202-637-5813
Facsimile: (202) 637-5910

Date Prepared: July 17, 1995

Name of Device and Name/Address of Sponsor

Series 9100+ PLUS Automated Differential and Non-Differential Hematology Analyzers

The Series 9100+ PLUS is comprised of the following three differential and one non-differential models:

- Model 9120 Interpretive 5-Part Differential Hematology Analyzer;
- Model 9118 Quantitative 3-Part Differential Hematology Analyzer;
- Model 9110 Quantitative Non-Differential Hematology Analyzer; and
- Model 9100 Rx Quantitative 1-Part Differential Hematology Analyzer

Sponsor

Serono Diagnostics, Inc.
100 Cascade Drive
Allentown, Pennsylvania 18103

Phone: 610-264-2800
Facsimile: 610-266-4361

Contact Person: Laurence A. Potter
Serono Diagnostics, Inc.
Phone: 610-266-4315
Facsimile: 610-266-4361

Common or Usual Name

Automated interpretive differential cell counter (applies to Model 9120)

Automated quantitative differential cell counter (applies to Models 9118 and 9000 Rx)

Automated cell counter (applies to Model 9110)

Classification Name

Automated differential cell counter (intended to flag or identify specimens containing abnormal blood cells)

Automated cell counter

Predicate Devices

The Company's Series 9100+ PLUS covered by this submission is substantially equivalent to other legally marketed automated differential and non-differential blood cell counters. Specifically, the differential hematology analyzers in the Series 9100+ PLUS are substantially equivalent to Serono Baker Diagnostics, Inc.'s System 9000+ Interpretive Diff Model Cell Counters (K911626/B), and the non-differential hematology analyzer in the Series 9100+ PLUS is substantially equivalent to Serono Baker Diagnostics, Inc.'s System 9000 Automated Cell Counter (K870603). (For convenience, these two predicate devices will hereafter be referred to together as the "predicate System 9000+/System 9000" whenever it is appropriate.)

Intended Use

Each of the four models within the Series 9100+ PLUS (i.e., Model 9120, Model 9118, Model 9110, and Model 9100 Rx) is intended for use as a fully automated hematology cell counter for the in vitro diagnostic testing of whole blood specimens. The Series 9100+ PLUS also is intended to flag or identify specimens containing abnormal blood cells.

Technological Characteristics and Substantial Equivalence

A. Description of the Series 9100+

The Series 9100+ PLUS is comprised of four models of hematology analyzers: Models 9120, 9118, 9110, and 9100 Rx. The most advanced hematology analyzer of the four models (i.e., the model with the greatest number of testing parameters) is the Model 9120, testing a total of 20 parameters. The other models in the Series 9100+ PLUS (i.e., Models 9118, 9110, and 9100 Rx) have exactly the same technological design and electronics as the Model 9120, except that each of these three models lacks one or more of the testing parameters and/or features offered by the Model 9120. This downgrading is achieved in models other than the Model 9120 simply by suppressing or eliminating the software functions that would otherwise allow each of those analyzers to test all of the possible parameters.

Three of the four models in the Series 9100+ PLUS (i.e., Models 9120, 9118, and 9100 Rx) contain a built-in 5-, 3-, or 1-Part Differential software package (respectively) that has the ability to perform interpretive 5-part and quantitative 3- or 1-part white cell histogram differentials. (It should be noted, however, that the non-differential Model 9110 can be upgraded to perform the same 5- or 3- part differential analyses performed by the Models 9120 and 9118, respectively, simply by replacing the relevant software modules in the lower tier model and by utilizing the Series 9100+ PLUS differential reagents instead of the non-differential reagents usually associated with the Model 9110.)

The interpretive report for the Model 9120 and the quantitative reports for the Model 9118 and the Model 9100Rx removes subjectivity and provides possible suggestions of interpretation of the white cell, red cell, and platelet histograms based on a computer comparison of the histogram pattern with a multiplicity of pre-set limits. The interpretive report for the Model 9120 does not provide positive identification of cell types, but it alerts the user to the possible presence of abnormally high or low concentrations of normal cell types, abnormal cell types, and abnormally small or large sizes of normal cell types. Both the interpretive and the quantitative reports also provide one or more messages that categorize suspected abnormalities.

The rate of determination for each model in the Series 9100+ PLUS is approximately one sample per 1.33 minutes. This rate includes the time from introduction of the whole blood sample to sample analysis, along with the display and printing of the test results. The system is totally automated with an internal dilution system.

Each model in the Series 9100+ PLUS has a cap piercer module that permits sampling of the blood specimens without removing the stopper from the blood vacuum collection tube. An "AutoSampler" module (denoted by the term "Ax") is optional and allows for the automatic mixing and sampling of multiple EDTA-anticoagulated blood specimens from a batch of closed 5 mL vacuum tubes. The AutoSampler also has a Bar Code Scanner option which enables the automatic identification entry of tubes labeled with a standard bar code. Additionally, a manual Bar Code Scanner is available which functions independently of the the AutoSampler, and the user may add the Bar Code Scanner option to each model of the Series 9100+ PLUS without adding the AutoSampler module.

A blood sample can be introduced to the hematology analyzer by one of five methods: (1) the whole blood mode (through the sample probe); (2) the prediluted (fingerstick) sample mode; (3) the platelet-rich plasma mode; (4) the cap piercer mode; or (5) the "Ax" option. Each model of hematology analyzer within the Series 9100+ PLUS uses the same methods to measure the given parameters. The Series 9100+ PLUS makes use of several reagents and supplies.

B. Substantial Equivalence of the Series 9100+ PLUS to the Serono Baker Diagnostics, Inc. System 9000+ Interpretive Diff Model Cell Counter and the Serono Baker Diagnostics, Inc. System 9000 Automated Cell Counter

The predicate devices also provide the same or similar functions, characteristics, and accessories as described above for the Series 9100+. Like the Series 9100+, the predicate Serono Baker Diagnostics, Inc. System 9000+ and System 9000 ("System 9000+/System 9000") are intended for use as fully automated hematology cell counters for the in vitro diagnostic testing of whole blood specimens. Like the Series 9100+, the predicate System 9000+/System 9000 also are intended to flag or identify specimens containing abnormal blood cells. Similarly, both the Series 9100+ PLUS and its predicate devices have similar performance specifications and testing results for such analyses as correlation coefficient, linearity, precision (both within-run and day-to-day), and accuracy.

In fact, the Series 9100+ PLUS and its predicates are almost identical in their design, functions, characteristics, and accessories. Along with having the same intended use, both the Series 9100+ PLUS and the predicate System 9000+ offer one model with a 5-part interpretive differential software package and two other models with with a 1- or 3-part quantitative differential software package

(respectively) to perform interpretive 1-, 3-, or 5-part white cell histogram differentials (i.e., Model 9020, Model 9018, and Model 9000 Rx, respectively, for the predicate System 9000+). Likewise, both the Series 9100+ PLUS and the predicate System 9000 offer a non-differential hematology analyzer which measures the same 10 parameters. Both the Series 9100+ PLUS and its predicates have a rate of determination of approximately one sample per minute, a cap piercer function, and an optional AutoSampler module.

Both the Series 9100+ PLUS and the predicates System 9000+/System 9000 have identical cycles of operation, and all offer the same methods for blood sample introduction to the hematology analyzer. The Series 9100+ PLUS and the predicate System 9000+/System 9000 also employ all of the same testing methods to measure each blood sample parameter. Furthermore, the predicate System 9000+/System 9000 utilize the exact same reagents and supplies/accessories as do the hematology analyzers in the Serono Series 9100+.

Although there are some differences between the Series 9100+ PLUS and its predicate System 9000+/System 9000, these differences are minor and raise no new questions of safety and effectiveness. The differences between the Series 9100+ PLUS and the predicate devices include: (1) removal of the on-board printer; (2) replacement of reagent level sensors with a software reagent tracking system; (3) reduction in initial sample volume; (4) expansion of claimed platelet linearity; and (5) addition of a Bar Code Scanner capability. However, these few differences in technological characteristics between the Series 9100+ PLUS and its predicate device are minor and do not present any new issues of safety or effectiveness.

Performance Data

The Series 9100+ PLUS was subjected to the following performance testing:

- Linearity Testing (in the whole blood mode)
- Precision, Within-Run
- Precision, Day-to-Day
- Accuracy, Whole Blood Mode
- Accuracy, Cap Piercer/Predilute/AutoSampler Modes (through mode-to-mode comparison with sample run in the whole blood mode)
- Carryover Testing

In all instances, the Series 9100+ PLUS functioned as intended. These test results demonstrated that the Series 9100+ PLUS is both effective for its intended use and functions in a substantially equivalent manner to the predicate devices.