

K981568

AUG 21 1998

510(k) SUMMARY

In accordance with the Safe Medical Devices Act of 1990, a 510(k) summary is provided pursuant to 21 C.F.R. § 807.92.

*Submitter's name, address, telephone number, contact person, and date on which summary was prepared.*

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Date Prepared: April 30, 1998

*Device name: trade or proprietary name and common or usual name.*

Common Name: Automated Differential Blood Cell Counter

Proprietary Name: MASCOT MD Hematology Analyzer Model MD 800

*Identification of the legally marketed device to which the submitter claims substantial equivalence.*

Coulter Model STKS  
Manufactured by Coulter Electronics, Inc.  
501(k) No. K885093

*Description of the MD 800*

**Description:**

In General. The MD 800 is a quantitative analyzer of peripheral human blood for *in vitro* diagnostic use in clinical laboratories. It performs an automated complete blood count (CBC) and a leukocyte differential on peripheral human blood. A sample volume of 20  $\mu$ L of whole blood is required. The instrument provides a printed report on 20 parameters.

Components. The MD 800 consists of five components:

- (1) A blood analysis instrument (the "instrument") with external cord and grounded

plug for connection to a standard 110V AC outlet.

Externally, this instrument has an external diluter probe for the intake of blood samples and a communications panel consisting of red and green LED lights, a communications screen which provides messages to prompt the operator, and a keypad for operator input.

Internally, the instrument in general consists of three precise, motorized syringes used to move the blood sample, a series of electronically controlled valves which direct its flow, cuvette used to mix reagents with measured quantities of the sample, a transducer chamber used to count the blood cells, another transducer chamber used to determine hemoglobin levels, connective tubing and wiring, the communications panel described above and a computer and related software program used to direct the instrument in taking a series of steps necessary to analyze the sample and produce a report.

(2) A reagent dispensing unit connected to the instrument by tubes and four reagents (described below in "Reagents") used in it.

(3) Calibration and control reagents consisting of a reagent used to calibrate the MD 800 as directed in the Manual and another reagent used according to good laboratory practices at the beginning and end of each group of samples, or in long runs, at established intervals to verify operation of the instrument (these reagents are described below in "Reagents").

(4) Probecenz™, a cleaning liquid described below in Reagents.

(5) A standard, off-the-shelf high resolution printer selected by the manufacturer to print the report of the analysis.

Reported Parameters. The MD 800 reports on the following parameters:

White Blood Cells (Leukocytes)	WBC
Red Blood Cells (Erythrocytes)	RBC
Hemoglobin Concentration	Hgb
Hematocrit (relative volume of erythrocytes)	Hct
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Corpuscular (erythrocyte) Hemoglobin	MCH
Mean Corpuscular (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte volume) Distribution Width	RDW
Platelet or Thrombocyte Count	Plt
Mean Platelet (thrombocyte) Volume	MPV
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%

Monocyte (number)	MO#
Monocyte (percent of WBC)	MO%
Basophil (number)	BA#
Basophil (percent of WBC)	BA%
Neutrophil (number)	NE#
Neutrophil (percent of WBC)	NE%
Eosinophil (number)	EO#
Eosinophil (percent of WBC)	EO%

**Reagents.** The MD 800 uses the following reagents:

(1) **diluent:** MULTI-CELL<sup>3</sup>, an azide-free isotonic electrolyte for diluting the blood sample, stabilizing the cell membranes, and conducting current in the sensing zone. The diluent maintains the integrity of the erythrocytes, leukocytes, and platelets;

(2) **lytic reagents:** CELLYSE XIH<sup>TM</sup> and CELLYSE XIIH<sup>TM</sup>, which are azide-free lytic reagents that (a) lyse erythrocytes, freeing hemoglobin from the lysed red blood cells and converting a substantial portion of it to a stable, cyanide-containing pigment, (b) reduce the size of cellular debris to avoid interference with leukocyte counts, and (c) slightly alter the WBC membranes to allow differentiating measurements to be made. The leukocyte membranes are physically maintained so as not to leave a bare nucleus;

(3) **cleaning agents:** CD CLEAN<sup>TM</sup>, a deproteinizer included in the reagent kit which prevents protein build up in the system; and PROBECLENZ<sup>TM</sup>, a cleaning liquid used according to instructions in the Operators Manual (pages 4-4, 4-6 and 8-2) used periodically to clean the instrument.

(4) **control material:** TECH-TROL<sup>TM</sup>, used at three levels, to monitor both the CBC and WBC differential parameters; and

(5) **calibrator:** MD CAL-KIT<sup>TM</sup>, which is used to calibrate the CBC parameters.

**How the MD 800 functions:**

After calibration and initial testing, the operator mixes a sample of EDTA-treated human blood, and causes the MD800 to aspirate a 20  $\mu$ L samaple of the blood sample into the instrument. After a few additional short steps, the instrument automatically performs all remaining functions necessary to complete the analysis of the blood sample. The operator has no other function except appropriate handling of the printed report. An analysis of a blood sample takes approximately 5 minutes.

Following a sequence of steps, the MD 800 creates both a red blood cell ("RBC") dilution and a white blood cell ("WBC") dilution using the HEMA-SET<sup>3</sup> reagents described below and then analyses the resulting dilutions. The steps are as follows:

(1) The instrument creates a stock dilution by drawing precise quantities of specific reagents (described below in "Reagents") from the reagent box and mixes them with 20  $\mu\text{L}$  of whole blood sample by opening valves and the operation of the motorized syringes. The sample is mixed by bubbling air through the measured reagent/blood sample mix. 10  $\mu\text{L}$  of the stock dilution is reaspirated into the aspirator probe and reserved for the RBC/Plt analysis.

(2) To determine WBC and hemoglobin, the instrument again draws precise quantities of specific reagents from the reagent box and mixes them with the remaining stock dilution. This dilution is again mixed by bubbling air through the reagent/blood stock dilution mix. This mixture is then passed into the hemoglobin module and hemoglobin levels are measured. The balance is then positioned at the entrance to the FOCUSED FLOW™ chamber for WBC analysis.

(3) A precisely measured portion of this mixture (50 $\mu\text{L}$ ) is injected by the motorized syringe into the FOCUSED FLOW™ chamber and is analyzed for leukocyte population. This chamber operates as follows: The chamber itself is tubular. In the middle, a funnel-shaped passageway narrows and then opens to the original diameter (see diagram at Tab 5). Clean MULTI-CELL<sup>3</sup>™ diluent is drawn into the instrument from the reagent box and injected under precisely controlled pressure at an angle into the wide end of the funnel so as to produce a circular, swirling action or vortex of clean "sheath" fluid spiraling into the narrow end of the funnel. At the same time, at the end of the chamber, diluent is extracted by a precisely controlled vacuum. Injection and vacuum pressure is created by the operation of two of the three precise, motorized syringes. The third syringe is then used to inject the blood sample mixture into the center of the vortex of sheath fluid, thus maintaining the physical integrity and characteristics of the blood cells. The swirling sheath fluid concentrates the blood sample in the center of the narrow end of the funnel which is the sensing zone. As individual blood cells pass into the sensing zone, the instrument generates multiple electronic signals around and through the blood cells. These are read by a transducer and recorded.

The reagents used in the mixture aid the multiple signals in determining cell size, cell membrane and intracellular composition. The reagents work in concert with the physiology of the cells' membranes. Cellular information is derived from the following sources: (1) the process of single cell analysis, (2) isometric pressures, (3) the absence of distorting shear forces on the cells, (4) the physiological "conditioning" of cell membranes, and (5) concomitant multiple signal generation and concomitant multiple signal acquisition.

The individual cellular information or data obtained in this way is processed by the computer using a patented mathematical algorithm named *Expectation Maximization (EM)*. The mathematical algorithm is attached at Tab 6, and is also discussed in the Hazard Analysis attached at Tab 7. Results obtained by use of the analysis allows for differentiation of the reported parameters for WBC.

The chamber is then flushed and prepared for the next sample.

(4) Again by the operation of electronically controlled valves and the precise, motorized syringes, the reserved 10 $\mu$ L of the original stock dilution is separately mixed with reagents. The dilution is mixed by bubbling air through the measured reagent/blood sample mix, and is then positioned at the entrance of the FOCUSED FLOW™ chamber for RBC/Plt analysis.

(5) 25 $\mu$ L of this reagent-blood sample mixture is then injected by the motorized syringe into the FOCUSED FLOW™ chamber and is analyzed in a similar way to determine RBC/Plt composition. Again the reagents assist the multiple electronic signals to distinguish cell types and composition. The cell information is again processed using the parts of mathematical algorithm referencing red blood cell parameters attached at Tab 8.

(6) The system then cleans itself in preparation for reuse, and prompts the operator that it is ready with the message, "Ready" and "Mix Sample."

(7) The printer provides a report of 20 parameters on a high-resolution form. The report covers leukocytes and the five normal cell types (Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils). It produces "flags" for abnormal/immature cells. The report also includes a three-dimensional cytogram of the leukocyte population and a three-dimensional cytogram of the RBC/Plt population.

#### **Scientific Concepts:**

Each of the parameters is measured by the MD800 based on the following scientific principles:

<b>WBC, RBC, Plt:</b>	Cells are guided through a patented Focused Flow micro-aperture where they are counted according to impedance variation.
<b>Hgb:</b>	A cyanide-containing pigment is measured by spectrophotometry through the optical part of the WBC device at a wavelength of 540 nm $\pm$ 1 nm.
<b>MCV:</b>	An electronic device measures the pulse heights generated by the passage of RBCs through the Focused Flow chamber. The stored values of the pulse heights (which are proportional to the volume of the individual RBCs) are sorted into a pulse height distribution the mean of which is proportional to the MCV.
<b>Hct, MCH, MCHC:</b>	These parameters are calculated from other measured

parameters.

**RDW:** This parameter is a coefficient of variation of the RBC distribution as a percent of average RBC size.

**MPV:** This parameter is derived from the accumulation of platelet data within the platelet population distribution.

**LY, MO, NE, EO, BA:** The leukocyte differential counts are obtained from volume and intracellular complexity measurements and processed according to a patented mathematical algorithm termed Expectation Maximization.

### **Significant Performance Characteristics of Device:**

The performance specifications of the MD 800 are shown at Figure 6-1

#### *Statement of intended use.*

The MD 800 is a multi-parameter, automated hematology analyzer used to perform *in vitro* diagnosis of peripheral human blood in clinical laboratories.

The MD 800 reports on the following parameters:

White Blood Cells (Leukocytes)	WBC
Red Blood Cells (Erythrocytes)	RBC
Hemoglobin Concentration	Hgb
Hematocrit (relative volume of erythrocytes)	Hct
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Corpuscular (erythrocyte) Hemoglobin	MCH
Mean Corpuscular (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte volume) Distribution Width	RDW
Platelet or Thrombocyte Count	Plt
Mean Platelet (thrombocyte) Volume	MPV
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%
Monocyte (number)	MO#
Monocyte (percent of WBC)	MO%
Basophil (number)	BA#
Basophil (percent of WBC)	BA%
Neutrophil (number)	NE#
Neutrophil (percent of WBC)	NE%
Eosinophil (number)	EO#
Eosinophil (percent of WBC)	EO%

FIGURE 6-1

**MASCOT™ MD 800 HEMATOLOGY SYSTEM SPECIFICATIONS**

DESCRIPTION	MD 800 SPECIFICATIONS	
<b>Parameters:</b>		
Leukocytes:	WBC, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#	
Erythrocytes:	RBC, Hb, HCT, MCV, MCH, MCHC, RDW	
Platelets:	PLT, MPV	
<b>Cytograms:</b>	Exclusive 3-D Displays of WBC Subpopulations, RBC/Platelet Populations	
<b>Sample Volume:</b>	20µL	
<b>Throughput:</b>	12 Specimens per Hour	
<b>Data Input/Output:</b>	Touch Keypad, LCD Display, Customized 8.5" x 11" High-Resolution Report with Exclusive 3-D WBC, RBC, and PLT Cytograms	
<b>Optional Output:</b>	Internal Data Storage. RS232 Port for External Computer Interface	
<b>Flagging:</b>	Automatic Distributional and Morphological Flagging, Hematologic Abnormality Charts	
<b>Power Requirements:</b>	47 - 63 Hz, 95 - 132 vAC, < 110 W *	
<b>Physical:</b>	<u>Analyzer</u>	<u>Printer</u>
Height:	30.5 cm. (12 in.)	17.6 cm. (6.9 in.)
Width:	27 cm. (10.5 in.)	34.7 cm. (13.7 in.)
Depth:	43 cm. (17 in.)	20.7 cm. (8.2 in.)
Weight:	11.3 kg. (24.8 lbs.)	2.6 kg. (5.7 lbs.)
<b>Operating Temperature:</b>	17°C - 32°C (62° - 90°F)	
<b>Precision:</b>	WBC <3.0 % c.v. @ 7.0 - 10.0 x 10 <sup>3</sup> /µL	
	RBC <3.0 % c.v. @ 4.0 - 5.0 x 10 <sup>6</sup> /µL	
	Hb <2.0 % c.v. @ 12.0 - 15.0 g/dL	
	MCV <1.0 % c.v. @ 80.0 - 90.0 fL	
	PLT <6.0 % c.v. @ 200 - 400 x 10 <sup>3</sup> /µL	
	MPV <4.5 % c.v. @ 7.0 - 9.0 fL	
<b>Linearity:</b>	WBC 0.1 - 200.0 x 10 <sup>3</sup> /µL	Limits: 0.4 or 5.0%
	RBC 0.01 - 18.00 x 10 <sup>6</sup> /µL	0.10 or 8.0%
	Hb 0.1 - 26.0 g/dL	0.3 or 3.0%
	MCV 40.0 - 290.0 fL	1.5 or 5.0%
	PLT 1 - 2000 x 10 <sup>3</sup> /µL	15 or 10%
	MPV 4.0 - 16.0 fL	2 or 5%

\* 185 - 264 vAC also available.

*Summary of the technological characteristics of the MD 800 in comparison to those of the Coulter STKS.*

A summary of the technological characteristics of the MD 800 in comparison to the MD 800 is attached as Figure 8-1.

The MD 800 and Coulter STKS report the same 20 hematological parameters. Although the MD 800 and Coulter STKS use somewhat different operating principles, the operation of both devices is based upon passing human peripheral whole blood diluted with reagents through a narrow passageway in which the dilute solution is passed through an electric current, and the differences in impedance recorded for each cell. The Coulter also uses laser analysis to supplement the results determined by reading the electronic field. The MD 800 does not because it uses a combination of different treatment of the blood cells by reagents and different mathematical algorithms to obtain equivalent results to the Coulter STKS. Both instruments analyze the information obtained using a mathematical algorithm applied by a computer. The results for the 20 parameters are communicated to the operator by both instruments.

Based on the extensive nonclinical and clinical testing performed on the MD 800 summarized below, it is clear that it is substantially equivalent to the Coulter STKS, and that any differences in technological characteristics between the new device and the predicate device do not affect the ability of the MD 800 to obtain substantially equivalent results to the Coulter STKS, or affect safety or effectiveness.

*Brief discussion of nonclinical tests.*

The MD 800 was tested in accordance with National Committee for Clinical Laboratory Standards, *Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods*, Approved Guideline, NCCLS Document H20-A, Villanova, PA, 1992. ("NCCLS H20-A"). Following that Guideline, precision (within run/short term; long-term stability; carryover) and accuracy (linearity) studies of the MD 800 were conducted at the clinical laboratory at Lawrence & Memorial Hospital in New London, Connecticut during 1997.

The MD 800 performed within the normal and expected range for automated hematology instruments when so tested according to NCCLS H20-A.

*Brief discussion of clinical tests.*

Three clinical studies were conducted. The first is a comparison test administered at the clinical laboratory of Lawrence & Memorial Hospital in New London, Connecticut. It

## COULTER STKS Vs. MASCOT™ MD 800 SPECIFICATIONS

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<b>Parameters:</b>																														
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Erythrocytes:	RBC, Hb, HCT, MCV, MCH, MCHC, RDW	RBC, Hb, HCT, MCV, MCH, MCHC, RDW																												
Platelets:	PLT, MPV	PLT, MPV																												
<b>Power Requirements:</b>	50 - 60 Hz, 90 - 125 vAC, 1650 W or 210 - 250 vAC	47 - 63 Hz, 95 - 132 vAC, < 110 W or 185 - 264 vAC																												
<b>Temperature:</b>	16° - 29.5°C (60° to 85°F)	17° - 32°C (62° to 90°F)																												
<b>Humidity:</b>	0 to 95% without condensation	0 to 96% without condensation																												
<b>Sample Stability:</b>	0 to 24 Hrs.	0 to 4 Hrs.																												
<b>Throughput:</b>	100 Samples/Hour (Mean)	12 Samples per Hour																												
<b>Sample Volume:</b>	Primary Mode - 250 µL Secondary Mode - 150 µL Secondary mode with F55 1mL	20 µL																												
<b>Waste:</b>	20-liter waste container or a chemically resistant open drain	20-liter waste container or a chemically resistant open drain																												
<b>Precision:</b>	WBC <1.7 % c.v. @ 10.0 x 10 <sup>3</sup> /µL RBC <0.8 % c.v. @ 5.0 x 10 <sup>6</sup> /µL Hb <0.8 % c.v. @ 15.0 g/dL /MCV <0.8 % c.v. @ 90.0 fL PLT <3.3 % c.v. @ 300 x 10 <sup>3</sup> /µL MPV <2.2 % c.v. @ 9.0 fL	WBC <3.0 % c.v. @ 7.0 - 10.0 x 10 <sup>3</sup> /µL RBC <3.0 % c.v. @ 4.0 - 5.0 x 10 <sup>6</sup> /µL Hb <2.0 % c.v. @ 12.0 - 15.0 g/dL MCV <1.0 % c.v. @ 80.0 - 90.0 fL PLT <6.0 % c.v. @ 200 - 400 x 10 <sup>3</sup> /µL MPV <4.5 % c.v. @ 7.0 - 9.0 fL																												
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FIGURE 8-1

compared the precision and accuracy of the MD 800 and Coulter STKS in a series of tests. In the second, a sensitivity study was conducted on the MD 800 in conformance with NCCLS H20-A, also at the clinical laboratory of Lawrence & Memorial Hospital to demonstrate its ability to perform according to accepted industry standards and its safety and effectiveness. In the third, the MD 800 analyzed excess blood samples at three sites, one of which was a point of use site at a pediatric clinic, and two of which were at hospital clinical laboratories.

The clinical study results indicate that the MD 800 performs in a manner substantially equivalent to the Coulter STKS and is safe and effective under conditions of actual use in both large clinical laboratories and point of use laboratories operated in conjunction with a medical office. The results of the clinical studies are reported below.

Subjects. Human peripheral blood was used in the studies. Samples were selected as appropriate for the clinical study.

#### Clinical Studies.

1. Study # 1: 215 excess patient recently drawn whole blood samples were selected from the whole blood samples available at Lawrence & Memorial Hospital clinical laboratories during the period of the study. Selection criteria was determined by the requirement that samples be selected in conformance with NCCLS H20-A. A distribution between abnormal and normal blood samples and a distribution among abnormalities was sought. Samples were initially analyzed on the Coulter STKS to determine distribution between abnormal and normals, and distribution among abnormalities.

Patient samples giving a morphologic positive result were eliminated from the white blood cell differential count portion of the correlation study, as recommended in NCCLS H20-A, resulting in a reduction of the samples for the WBC differential count portion only to 129.

After a sample was selected, it was promptly analyzed by the MD 800 and the Coulter STKS and the results recorded. The clinical laboratory workers conducting the analysis the second time were not aware how a sample had been categorized in the first screening.

Following NCCLS H20-A recommendations, the samples were run twice on the MD 800 and the average used in the correlations. Similarly, two technicians each did a WBC differential manual count on all samples, and their results were averaged for the purposes of the correlation.

Results: The correlation coefficient, slope and y-intercept were determined for each parameter. The results obtained by the MD 800 are comparable to those obtained by the Coulter STKS, and the correlation coefficients for each parameter fall well within the accepted range for that parameter. The results obtained by the MD 800 and the manual WBC differential count likewise fall well within the accepted range for each parameter

tested, and confirm both the comparable performance of the MD 800 and its safety and effectiveness. The resulting correlations fall well within the expected range.

2. Study # 2: This study was a sensitivity study.

The same 215 excess blood samples selected for Study # were used for this study. The initial selection criteria and methodology of selection for that study were therefore used for this study also. All 215 samples initially selected for study # 1 were included in this sensitivity study. The subset of flagged samples excluded from the Correlation Study were not excluded from this study, in conformance with the standards for a sensitivity study recommended by NCCLS H20-A.

After a sample was selected, it was promptly analyzed in two separate runs by the MD 800 and the abnormalities indicated by the MD 800 as relevant flags were then recorded. Results for the same samples were also determined using a manual differential count. The clinical laboratory workers operating the MD 800 were not aware how a sample had been categorized in the first screening or in any other MD 800 run.

The MD 800 records distributional abnormalities and morphological abnormalities. The distributional and morphological abnormalities as reported by the MD 800 were compared to the results obtained by the manual reference method in accordance with NCCLS H20-A. A false positive (FP) or false negative (FN) means that the manual count obtained a different result from the MD 800.

Out of 129 samples used in the distributional abnormality part of the study, there was one false negative and four false positives. Of 215 samples used in the morphological abnormality part of the study, there were two false negatives and 17 false positives. False positives are considered of considerably lesser significance than false negatives since a reported false positive will result in additional study, usually a manual count.

The results from the MD 800, the Coulter STKS, and the manual WBC count were recorded. The manual count is recorded as the results from each technician, and the average of both. For the purposes of analysis and tabulation, the average of both technicians was used for the manual WBC count to minimize the effects of human error.

This sensitivity study obtained results well within the expected range for automated hematological blood analyzers. The CDC MD 800's sensitivity results for the distributional abnormalities gave a more favorable false negative ratio (2.27%) versus the Coulter STKS (7.5%). The CDC MD 800 sensitivity results for the morphological abnormalities gave a more favorable false negative (2.86%) versus the Coulter STKS (10.0%). A low false negative ratio assists clinicians in not missing an abnormality. The low incidence (less than 3%) of false negatives is particularly significant.

Study # 3: This study was conducted at three separate sites: hospital clinical

laboratories at Lawrence & Memorial Hospital, New London, Connecticut; Norwalk General Hospital, Norwalk, Connecticut; and the point-of-use clinical laboratory at Children's Medical Associates, P.C., a three pediatrician out-patient doctor's office located in Ansonia, Connecticut. All three laboratories are subject to and operated in accordance with applicable requirements of CLIA 1988.

The participating clinical laboratories were instructed to analyze excess fresh human blood samples according to the operating instructions for the MD 800 and for their regular automated hematology analyzer, following normal operating procedures for their laboratories, until they had each analyzed forty or more samples, and record the results for each over a period of days.

The study analyzed 147 whole human blood samples, 57 at Norwalk Hospital, 40 at Lawrence & Memorial Hospital and 50 at Children's Medical Hospital. Correlation coefficients obtained at each site are very similar to the correlation coefficients obtained in the comparison study reported above in which the precision, accuracy and sensitivity of the MD 800 and Coulter STKS were compared, parameter by parameter. All of the directly measured parameters at each site have a very high correlation (.90 or higher). Most of the indices likewise have a correlation of .90 or higher. MCHC, MCH and MPV have lower coefficients, but those results are consistent with the same level of correlation obtained in the comparative precision, accuracy and sensitivity tests conducted on the MD 800 and Coulter STKS, and fall within the normal range of correlation expected for hematology analyzers for those parameters. The correlation coefficients fall well within the normal range expected under conditions of field use in hospitals or point of use.

*The conclusions drawn from clinical and nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.*

Based on these data, the MASCOT Hematology Analyzer is as safe and effective and performs as well or better than the predicate device for the intended use of obtaining an *in vitro*, 20 parameter hematological profile of whole peripheral blood in clinical laboratories.

When tested in the nonclinical tests summarize above, the MD 800 showed results in within/run, long term stability, carryover and linearity that fall well within the range expected for human hematology analyzers in general, and, as shown by comparison to the specifications of the Coulter STKS at Figure 6-2, well within the range of performance of the Coulter STKS.

When tested in three clinical studies, the performance of the MD-800 was either equivalent or better than the Coulter STKS, both under hospital clinical laboratory conditions and in the field, including use in a point of use clinical laboratory.

In addition, the nonclinical and clinical tests demonstrate that the MD 800 performs well within the expected range for a human hematology analyzer under tests recommended by

NCCLS H20-A for the evaluation of the safety and effectiveness of such analyzers, demonstrating that the device is as safe and effective as the Coulter STKS.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 21 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

CDC Technologies, Inc.  
c/o Mr. George J. Wallace  
Eckert Seamans Cherin & Mellott, LLC  
1250 24<sup>th</sup> Street, N.W., 7<sup>th</sup> Floor  
Washington, DC 20037

Re: K981568/S1  
Trade Name: MASCOT MD Hematology Analyzer Model MD 800  
Regulatory Class: II  
Product Code: GKZ  
Dated: July 22, 1998  
Received: July 23, 1998

Dear Mr. Wallace:

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 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). 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.

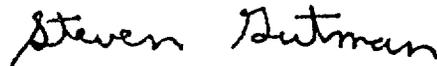
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2

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/dsma/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): unknown (not assigned yet)

Device Name: MASCOT MD Hematology Analyzer Model MD 800

Indications for Use:

The MD 800 is a multi-parameter, automated hematology analyzer used to perform *in vitro* diagnosis of peripheral human blood in clinical laboratories.

The MD 800 reports on the following parameters:

White Blood Cells (Leukocytes)	WBC
Red Blood Cells (Erythrocytes)	RBC
Hemoglobin Concentration	Hgb
Hematocrit (relative volume of erythrocytes)	Hct
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Corpuscular (erythrocyte) Hemoglobin	MCH
Mean Corpuscular (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte volume) Distribution Width	RDW
Platelet or Thrombocyte Count	Plt
Mean Platelet (thrombocyte) Volume	MPV
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%
Monocyte (number)	MO#
Monocyte (percent of WBC)	MO%
Basophil (number)	BA#
Basophil (percent of WBC)	BA%
Neutrophil (number)	NE#
Neutrophil (percent of WBC)	NE%
Eosinophil (number)	EO#
Eosinophil (percent of WBC)	EO%

*Approved for Peter...*  
 (Division Sign-Off)  
 Division of Clinical Laboratory Devices  
 510(k) Number K981568/S1

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)