

K983562

NOV 3 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.*

**CDC Technologies, Inc.  
One Great Hill Road  
Oxford, CT 06478  
(203) 888-2323  
FAX: (203) 888-4828**

**Contact: David C. DeCava, V.P. of Operations**

**Date Prepared: October 12, 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 700**

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

**MASCOT MD Hematology Analyzer Model MD 800  
Manufactured by CDC Technologies, Inc.  
510(k) No. K981568**

*Description of the MD 700*

### **Description:**

In General. The MD 700 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 15 parameters.

Components. The MD 700 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 700 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 700 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
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%
Monocyte (number)	MO#

Monocyte (percent of WBC)	MO%
Granulocyte (number)	GR#
Granulocyte (percent of WBC)	GR%

Reagents. The MD 700 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 700 functions:**

After calibration and initial testing, the operator mixes a sample of EDTA-treated human blood, and causes the MD 700 to aspirate a 20  $\mu$ L sample 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 700 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  $\mu$ 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  $\mu$ 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 (50μL) 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 5, and is also discussed in the Hazard Analysis attached at Tab 6. 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 10μL 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) 25µL 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 15 parameters on a high-resolution form. The report covers leukocytes and three normal cell types (Lymphocytes, Monocytes, and Granulocytes). It produces "flags" for abnormal/immature cells. The report also includes a three-dimensional cytogram of the leukocyte population.

#### **Scientific Concepts:**

Each of the parameters is measured by the MD 700 based on the following scientific principles:

WBC, RBC, Plt:	Cells are guided through a patented Focused Flow micro-aperture where they are counted according to impedance variation.
Hgb:	A cyanide-containing pigment is measured by spectrophotometry through the optical part of the WBC device at a wavelength of 540 nm ± 1 nm.
MCV:	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.
Hct, MCH, MCHC:	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.

GR, LY, MO:

The leukocyte differential counts are obtained from volume and intracellular complexity measurements and processed according to a patented mathematical algorithm termed Expectation Maximization. Granulocytes are the arithmetic sum of eosinophils, neutrophils and basophils.

**Significant Performance Characteristics of Device:**

The performance specifications of the MD 700 are shown at Figure 6-1

*Statement of intended use.*

The MD 700 is a multi-parameter, automated hematology analyzer used to perform *in vitro* diagnosis of peripheral human blood in clinical laboratories.

The MD 700 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
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%
Monocyte (number)	MO#
Monocyte (percent of WBC)	MO%
Granulocyte (number)	GR#
Granulocyte (percent of WBC)	GR%

FIGURE 6-1

MASCOT™ MD 700 HEMATOLOGY SYSTEM SPECIFICATIONS

DESCRIPTION	MD 700 SPECIFICATIONS	
<b>Parameters:</b>		
Leukocytes:	WBC, GR%, GR#, LY%, LY#, MO%, MO#	
Erythrocytes:	RBC, Hb, HCT, MCV, MCH, MCHC, RDW	
Platelets:	PLT	
<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>	<b>Analyzer</b>	<b>Printer</b>
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	
<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%

\* 185 - 264 vAC also available.

*Summary of the technological characteristics of the MD 700 in comparison to those of the MD 800.*

The MD 700 analyses human peripheral blood by passing electronic waves through precisely measured dilutions of the blood, and analyzing the results using software which relies upon a patented mathematical algorithm to determine the count and percent of each parameter reported.

The fundamental scientific technology of the MD 700 has not changed from that of the MD 800. MD 800 and MD 700's intended use are the same. The reports provided by the two devices are different --

- The MD 800 provides a three-dimensional cytogram of the leukocyte population and a three-dimensional cytogram of the RBC/Plt population. The MD 700 provides only a three-dimensional cytogram of the leukocyte population.
- The MD 800 reports 20 parameters. The MD 700 reports 15 parameters. Thirteen of these parameters are the same in the two devices. However, the MD 700 does not provide mean platelet (thrombocyte) volume, and offers only a three part WBC differential, consisting of six parameters (3 actual count and 3 related percentages) while the MD 800 provides a five part differential consisting of ten parameters (5 actual count and 5 percentages).

This is a special 510(k). The non-clinical and clinical studies upon which the 510(k) of the MD 800 and its reagents were cleared are relied upon with respect to the MD 700. The MD 700 is as safe and effective as the MD 800, the predicate device, because the fundamental scientific technology of the MD 700 has not changed from that of the MD 800.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 3 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

CDC Technologies, Inc.  
C/O 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: K983562  
Trade Name: MASCOT MD Hematology Analyzer, Model MD 700  
Regulatory Class: II  
Product Code: GKZ  
Dated: October 12, 1998  
Received: October 13, 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.

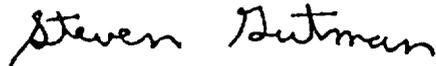
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

A handwritten signature in cursive script that reads "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): unknown (not assigned yet)

Device Name: MASCOT MD Hematology Analyzer Model MD 700

Indications for Use:

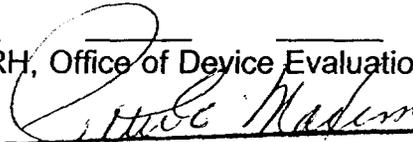
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Granulocyte (number)	GR#
Granulocyte (percent of WBC)	GR%
Lymphocyte (number)	LY#
Lymphocyte (percent of WBC)	LY%
Monocyte (number)	MO#
Monocyte (percent of WBC)	MO%

(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 1983562

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)