K961803

Micro Diagnostics Corporation

JUL - 5 1996

June 21, 1996

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Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville MD 20850

RE: K961803, Submission 510(k) Summary for Spuncrit™

Dear Sir or Madam:

A summary of the safety and effectiveness information upon which substantial equivalence is based as follows:

CLASSIFICATION: Class II Hematocrit Centrifuge

PROPRIETARY NAME: Spuncrit™ (Model DRC-40)

PRODUCTS UPON WHICH SUBSTANTIAL EQUIVALENCE IS BASED:

- Compur M1100 Minicentrifuge
  FDA No. K850391
  Date: May 10, 1985

SIMILARITIES TO PREDICATE DEVICES CURRENTLY ON THE US MARKET

A) Predicate's Name and Manufacturer Address

Hematocrit

- Compur M1100 Hematocrit System
  Bayer Diagnostic + Electronic GmbH
  Steinerstrasse 15
  8000 Muchen 70
  Germany
  C/O Hans J. Brouwers and Associates
  Box 823
  Mt Prospect, IL 60056
  FDA Reference No. K850391

A1) Comparison of Spuncrit™ to Compur (Predicate Device)

MICRO DIAGNOSTICS SPUNCRIT™	COMPUR M1100
o Micro Hematocrit Centrifuge	o Micro Hematocrit Centrifuge
o Operations Manual	o Operation Manual
o Battery Charger	o Battery Replacement
o 100 Micro Capillary/ Micro Capillary Holders (heparinized)	o 100 Capillaries (heparinized)

A2) The general features of the Spuncrit™ (Model DRC-40) as compared to the Compur M1100 Minicentrifuge.

SPUNCRIT™	COMPUR M1100
o General Laboratory Device	o General Laboratory Device
o Methodology: Centrifugal	o Methodology: Centrifugal
o Measures Hematocrit	o Measure Hematocrit
o Battery Operated	o Battery Operated
o Portable, Hand-Held	o Portable, Hand-held
Safety Features:	Safety Features:
(1) Cover Lock	(1) Cover Lock
(2) Low Battery Charge Indicator	(2) Low Battery Charge Indicator
(3) Motor failure indicator	(3) No such feature
o Optically read (digital readout)	o Manual, visual read

o Uses plastic disposable	o Uses glass disposable
o Range 14% to 57%	o Range 10% to 80%
o Operates at 10,000 RPM	o Operates at 11,500 RPM
o RCF= 4260	o RCF=5396
o Rotor Radius= 1.5 inches	o Rotor Radius= 1.5 inches

A3) The safety features of the Spuncrit™ as compared to the Compur M1100 Minicentrifuge.

SPUNCRIT™	COMPUR M1100
COVER LOCK	COVER LOCK
Mechanical lock switch which prevents cover from being opened while centrifuge is in operation	Mechanical lock switch which prevents cover from being opened while centrifuge is in operation
MECHANICAL BRAKE	MECHANICAL BRAKE
In the event the cover is opened prior to the Spuncrit completing the 150 second cycle time the rotor automatically is braked, stopping its rotation within a few seconds	No such feature
LOW BATTERY CHARGE	LOW BATTERY CHARGE
Digital display reads out "C" indicating to operator to charge batteries	An illuminated red LED indicates batteries need to be replaced
INSTRUMENT MALFUNCTION	INSTRUMENT MALFUNCTION
In the event of an electronic failure within the instrument the digital readout will not display "8's", as the DRC-40 is running.	No such feature

A4) Comparative data (Performance/Effectiveness Information) between the Spuncrit™ (Model DRC-40) and Compur's M1100 Minicentrifuge.

RESULTS OBSERVED WHEN OPERATING THE SPUNCRIT

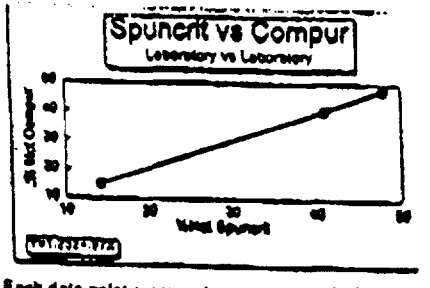
COMPARISON DATA

An "In Service" to explain the operation of the Spuncrit was performed in each of the locations. Approximately 10 minutes were utilized for training of persons operating the Spuncrit. The comparative study at each location included a total of 45 whole blood samples encompassing three levels ranging from below the normal range to the upper level of the normal range. The samples were split such that each location ran 15 samples at each level.

Spuncrit operating in a Laboratory:

- Typical laboratory with technician running the Spuncrit

N = 45
Range = 14% Hct to 49% Hct
R = .99

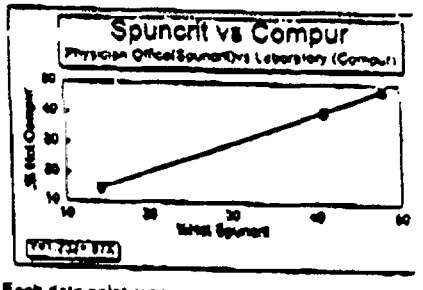


Each data point represents an average of 15 whole blood samples.

Spuncrit operating in Physician Office - #1

- Physician Office employs six Physicians with nurse running Spuncrit.

N = 45
Range = 14% Hct to 49% Hct
R = .99

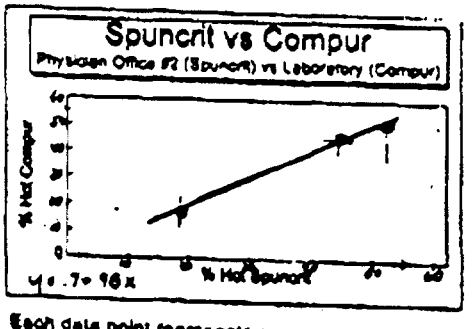


Each data point represents an average of 15 whole blood samples.

Spuncrit operating in Physician Office - #2

- Physician Office employs twelve physicians with a nurse running Spuncrit

N = 45
Range = 19% Hct to 53% Hct
R = .99

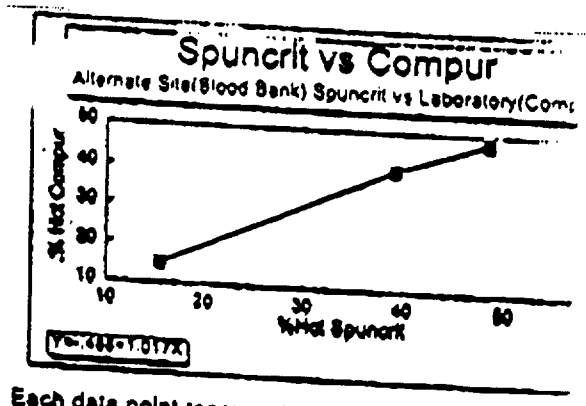


Each data point represents an average of 15 whole blood samples.

Spuncrit operating in an Alternate Site:

- Blood Bank with a Phlebotomist running the Spuncrit.

N = 45
Range = 14% Hct to 49% Hct
R = .99



Each data point represents an average of 15 whole blood samples.

PRECISION DATA

The precision study was performed within the physician office and another alternate site;a blood bank. Assayed whole blood controls were used in the precision study. Three levels of controls were used. A total of fifteen(15) samples were processed per each level for a total of 45 samples. The range varied from below the normal range to slightly above the normal range for the hematocrit. The study was repeated utilizing assayed whole blood controls from the same lot number seven(7) days after the first study.

WITHIN RUN PRECISION DATA

PHYSICIAN OFFICE # 1

Day One(Hematocrit)				Day Seven(Hematocrit)		
Level 1	**Level 2**	**Level 3**		**Level 1**	**Level 2**	**Level 3**
18.1	30.8	46.3	$\bar{X}$	16.8	32.4	46.4
.26	.94	1.03	SD	.77	.63	.63
.01	.03	.02	Cv	.04	.02	.02
15	15	15	N	15	15	15

PHYSICIAN OFFICE # 2

Day One(Hematocrit)				Day Seven(Hematocrit)		
Level 1	**Level 2**	**Level 3**		**Level 1**	**Level 2**	**Level 3**
17.9	33.5	46.1	$\bar{X}$	17.4	32.7	47.7
.70	.52	.74	SD	.64	.59	.59
.04	.02	.02	Cv	.04	.02	.01
15	15	15	N	15	15	15

ALTERNATE SITE (BLOOD BANK) # 3

Day One(Hematocrit)				Day Seven(Hematocrit)		
Level 1	**Level 2**	**Level 3**		**Level 1**	**Level 2**	**Level 3**
18.6	33.7	47.3	$\bar{X}$	18.8	33.4	47.5
.51	.88	1.11	SD	.68	.51	.52
.03	.02	.02	Cv	.04	.02	.01
15	15	15	N	15	15	15

BETWEEN RUN PRECISION DATA

Day One and Day 7 (Hematocrit)

Physician Office #1		$\bar{X}$	SD	Cv	N
	Level 1	17.4	.92	.05	2
	Level 2	31.6	1.13	.04	2
	Level 3	46.4	.07	<.01	2

Physician Office #2		$\bar{X}$	SD	Cv	N
	Level 1	17.6	.35	.02	2
	Level 2	33.1	.56	.02	2
	Level 3	46.9	1.13	.02	2

Alternate Site Blood Bank # 3		$\bar{X}$	SD	Cv	N
	Level 1	18.7	.14	.01	2
	Level 2	33.6	.21	.01	2
	Level 3	47.4	.14	<.01	2

Level 1,2,3 whole blood controls were Para 4 from Steck Laboratories Lot Numbers 61410065,61410066, and 61410067 respectively. Hematocrit values(%) for Streck controls are 16 +3 or -3, 32 +4 or -4,and 47 +5 or -5 respectfully.

NOTE:

An additional precision study was performed in a typical laboratory with 10 whole blood samples run at each level, a total of five (5) levels were used. The range varied from the lower end of the Spuncrit to the highest end of the Spuncrit. this study was repeated utilizing the same whole blood samples 13 days after the first study.

Whole blood samples (5 levels, A through E) were run on Day 1 and Day 13. These samples were prepared from the same lot, run on two different dates (Day 1 and Day 13).

WITHIN RUN PRECISION DATA

LABORATORY LOCATION

	DAY ONE (Hematocrit)				DAY 13 (Hematocrit)			
	$\bar{X}$	SD	Cv	N	$\bar{X}$	SD	Cv	N
LEVEL A	14.1	.32	.02	10	14.6	.52	.04	10
LEVEL B	29.3	.48	.02	10	30.3	.67	.02	10
LEVEL C	37.3	.48	.02	10	36.8	.92	.02	10
LEVEL D	53.6	.58	.01	10	52.5	1.51	.02	10
LEVEL E	56.3	.68	.01	10	56.6	.52	.01	10

BETWEEN RUN PRECISION DATA

LABORATORY LOCATION

DAY ONE and DAY THIRTEEN (Hematocrit)

	$\bar{X}$	SD	Cv	N
LEVEL A	14.4	.35	.02	2
LEVEL B	29.8	.71	.02	2
LEVEL C	37.1	.35	.02	2
LEVEL D	53.1	.78	.02	2
LEVEL E	56.4	.21	<.01	2

CONCLUSION: Based on the above information it is believed that the two products are substantially equivalent and the results provided by the Spuncrit provide the same clinical utility as the Compur M1100 Centrifuge for Hematocrit.

A6) Limitations of Procedure

- o Hematocrit
- o Estimated Hemoglobin

There are no known interfering substances that will interfere with the Hematocrit determination performed by the Spuncrit. However, severly hemolyzed blood should not be used in determining the Hematocrit by the Spuncrit.

The range of the Spuncrit for Hematocrit is 14% to 57%. The estimated Hemoglobin range is from 12.2 g/dL to 18.2 g/dL. The estimated Hemoglobin only estimates Hemoglobin as a function of the PCV. The estimated Hemoglobin is not representative of anemic problems. As a result the Spuncrit will only estimate the Hemoglobin for normal range only. Genetic Anemias or anemia caused by chronic disease states will not be estimated.