Section 9. 510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: BK050056

Date of 510K submittal: July 12, 2005

Submitter's info:

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Device name:

- Trade name: UltraCrit Hematocrit Measurement Device
- Common name: Automated Hematocrit Instrument

- Trade name: UltraChek Reference Controls
- Common name: Hematology quality control material

Establishment Registration Number: 1721649

Classification Information:

- Product Code: GKF
- Panel name: Hematology
- Device class: Class II
- Regulation number: 864.5600

- Product Code: GLK
- Panel name: Hematology
- Device class: Class II
- Regulation number: 864.8625

UltraCrit Device Intended use:

To quantitatively measure hematocrit (Hct) levels in human whole blood for the purpose of screening suitable adult blood donors for the blood banking industry.

- Analyte to be measured: Hematocrit
- Type of test: quantitative
- Specimen type: finger stick or venous

Device Indications For Use:

- Target patient population: adult blood donors
- The condition to be screened: suitability to donate blood
- Physiological purpose: measure hematocrit level

Reference Controls Intended use:

UltraChek Reference Controls are intended to monitor and evaluate the analytical performance of the UltraCrit device for the measurement of hematocrit.

- Analyte to be measured: Hematocrit
- Type of test: quantitative
- Specimen type: finger stick or venous

Reference Controls Indications For Use:

- Analyte to be measured: Hematocrit
- Device: To be used only for the UltraCrit device
- Number of Levels: 3

Device to which substantial equivalence is claimed (Predicate Device):

- Trade name: HemataSTAT II
- Common name: Hematocrit Measuring Device
- Full product code: JPI
- Panel name: Hematology
- Device class: Class II
- Regulation number: 864.6400
- Manufacturer's info:
  - Separation Technology, Inc.
  - 1096 Rainer Drive
  - Altamonte Springs, FL 32714
- 510K number: - K890849

Comparison with predicate device:

The performance characteristics of the UltraCrit system (device and Reference Controls) are similar to the HemataSTAT II system (as shown in Table 1). Differences between the devices are also discussed below in Table 1.

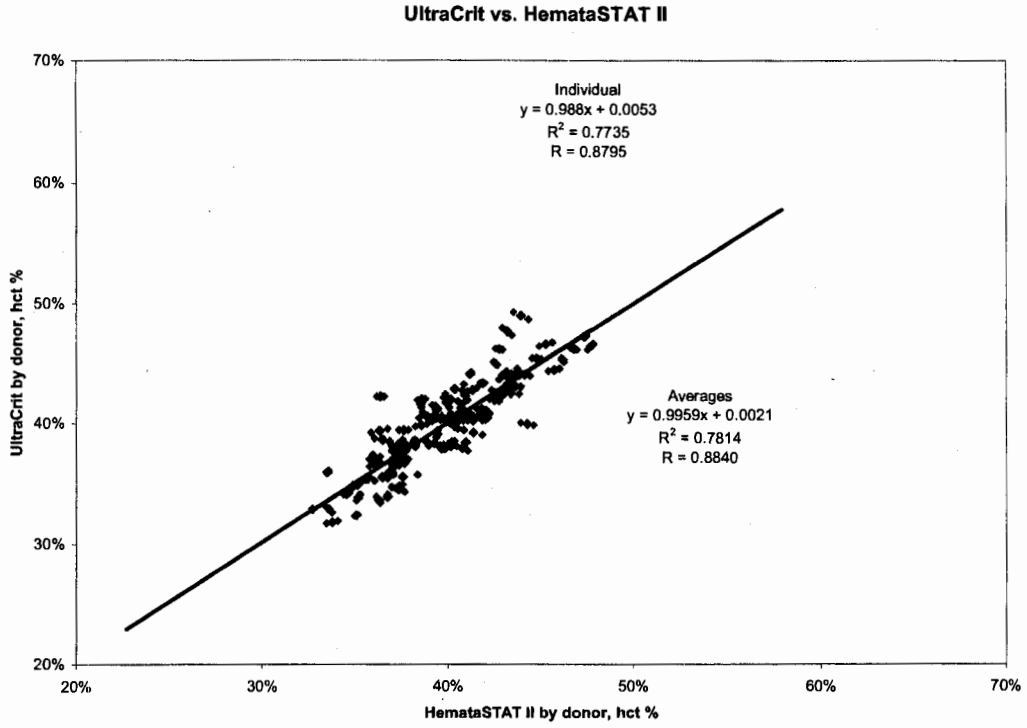
Similarities			
Item	**Description**	**Predicate Device – HemataSTAT II** K890849	**UltraCrit**
Intended Use/Test Objective	Quantitative determination of hematocrit in the whole blood of humans	Yes	Yes
Product Type	Hematocrit measuring device	Yes	Yes
Specimen Type	Human whole blood	Yes	Yes
Specimen Collection	Venous or capillary blood	Yes	Yes
Use of QC fluid	Dispense from QC fluid container into fill/capillary tube	Yes	Yes
Differences			
Item	**Description**	**Predicate Device – HemataSTAT II**	**UltraCrit**
Operating Procedure	Determination of hematocrit	Manual	Automatic
Operating Procedure	Determination of hematocrit	• Insert blood sample in device • Start analysis • Remove sample and make manual reading	• Insert blood sample in device • Start analysis • Device gives automatic reading
Methodology	Determination of hematocrit	Centrifugal separation of blood components and visual interpretation of hematocrit data	Measurement of acoustic pulse through blood sample and automatic hematocrit determination

Differences			
Item	**Description**	**Predicate Device – HemataSTAT II**	**UltraCrit**
Performance	Linearity	16 – 60% Hct	10.3 - 72.0% Hct
Performance	Precision	≤ 4.6% CV	≤ 0.8% CV
Performance	Accuracy	≤ 0.5% Hct	≤ 0.4% Hct
Performance	Glucose interference	NA	37 mg/dL to 245 mg/dL showed 0.76 to -0.49 hematocrit effect
Performance	K3EDTA interference	NA	4 X normal concentration showed 1.96 to 0.62 hematocrit effect
Performance	Hemoglobin interference	NA	10% hemolyzed RBC showed 0.608 to -0.463 hematocrit effect
Performance	Total serum protein interference	NA	7.3 to 11.6 g/dL showed a proportional effect where a 1.7 g/dL increase resulted in a 1.0 Hct increase
Performance	Fat (as triglycerides plus cholesterol) interference	NA	186 to 473 mg/dL showed a negative proportional effect where a 219 mg/dL increase resulted in a 1.0 Hct decrease.

VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and HemataSTAT II

Site 1, UC vs HemataSTAT, Individual Values

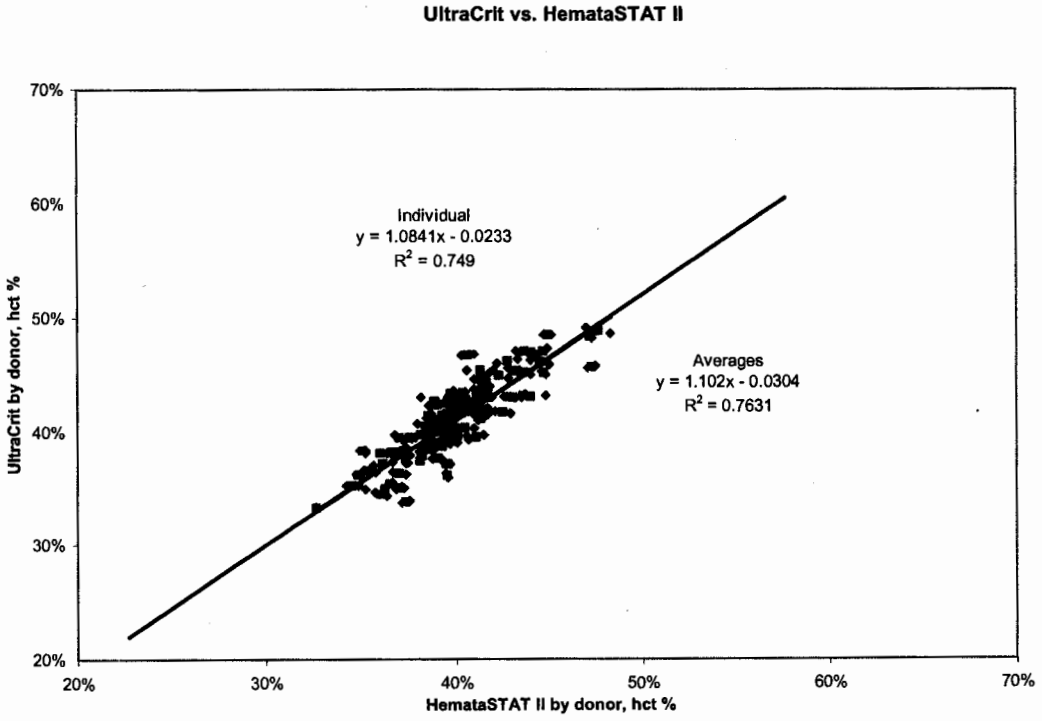
Regression Statistics		at 38% HemataSTAT	UC =38.07%
Multiple R	0.879466		
R Square	0.773460	95 % Lower Confidence Limit	37.82%
Adjusted R Square	0.77230		
Standard Error	0.017929	95 % Upper Confidence Limit	38.33%
Observations	198		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and HemataSTAT II

Site 2, UC vs HemataSTAT, Individual Values

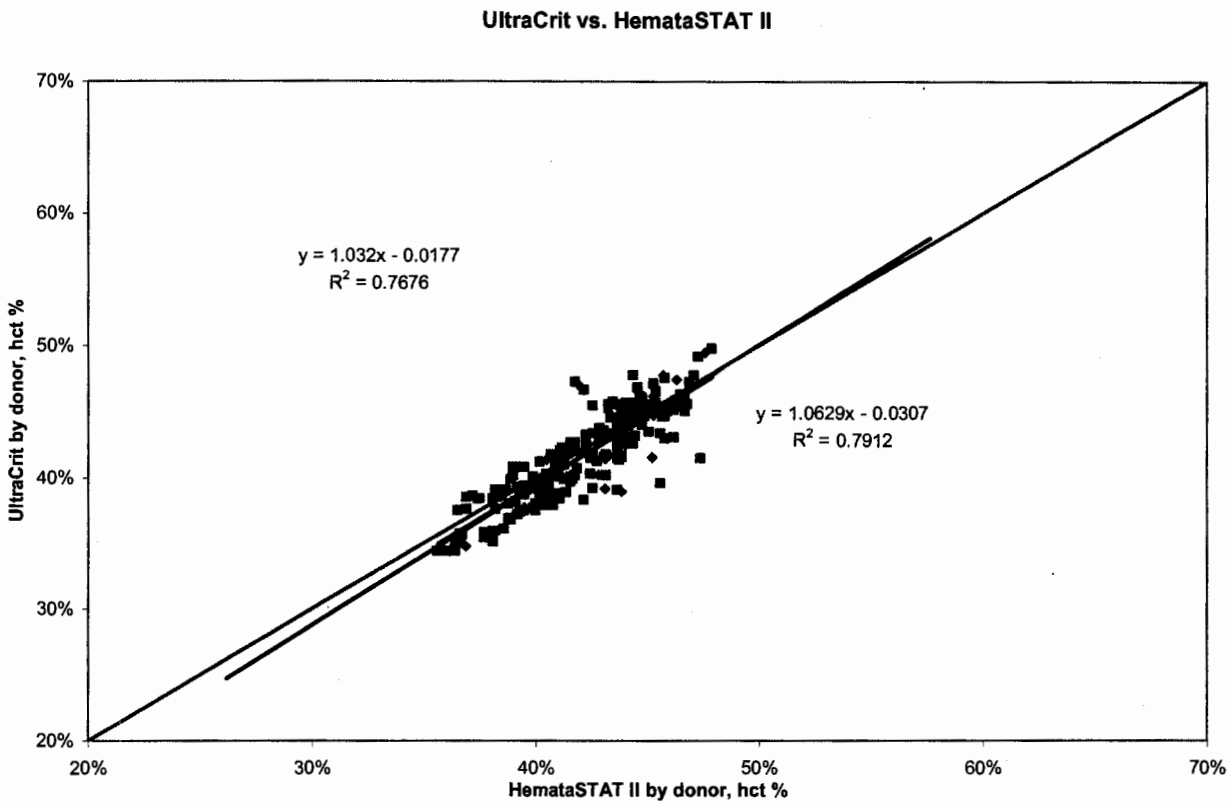
Regression Statistics		at 38% HemataSTAT	UC = 38.87%
Multiple R	0.865434		
R Square	0.748976	95 % Lower Confidence Limit	38.59%
Adjusted R Square	0.747669		
Standard Error	0.017395	95 % Upper Confidence Limit	39.14%
Observations	194		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and HemataSTAT II

Site 3, UC vs HemataSTAT, Individual Values

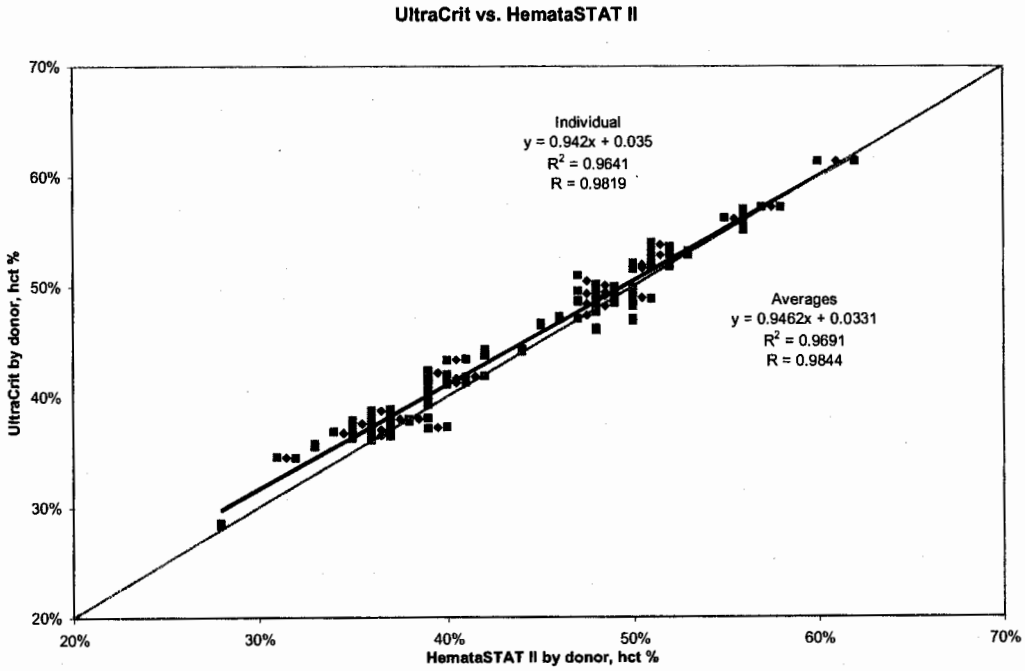
Regression Statistics		at 38% HemataSTAT II	UC=37.45%
Multiple R	0.876117		
R Square	0.767581	95 % Lower Confidence Limit	37.21%
Adjusted R Square	0.766371		
Standard Error	0.015981	95 % Upper Confidence Limit	37.69%
Observations	194		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and HemataSTAT II

Site 4, UC vs HemataSTAT, Individual Values

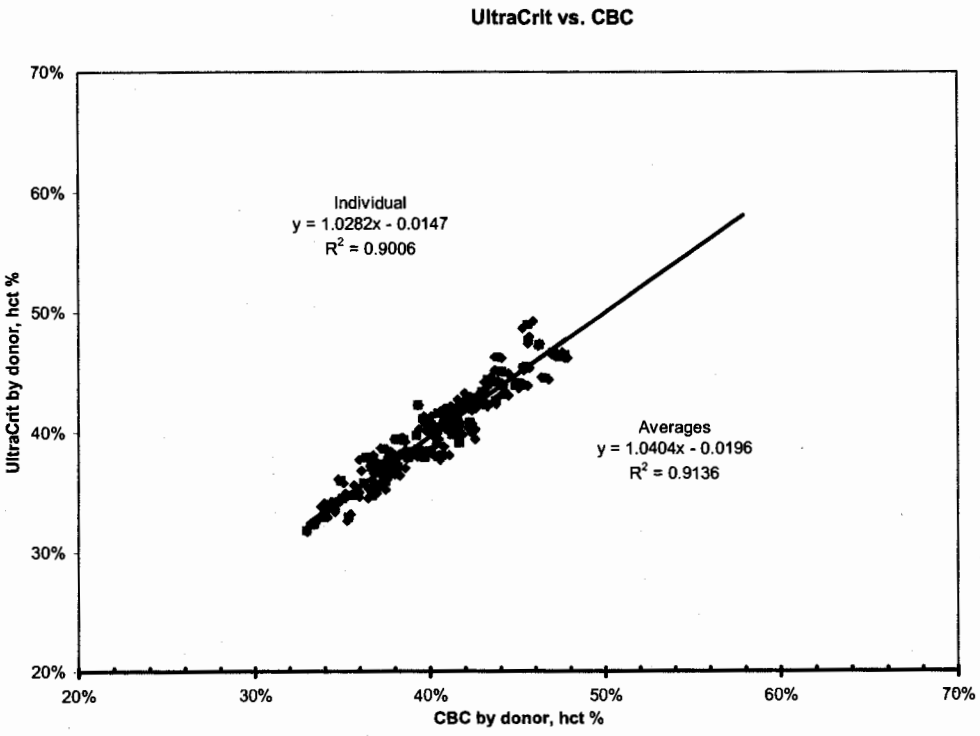
Regression Statistics		at 38% HemataSTAT II	UC = 39.29%
R	0.9819		
R squared	0.9641	95 % Lower Confidence Limit	39.04%
Adjusted R squared	0.9638		
Standard Error	0.0133	95 % Upper Confidence Limit	39.54%
Observations	120		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and CBC

Site 1, UC vs CBC, Individual Values

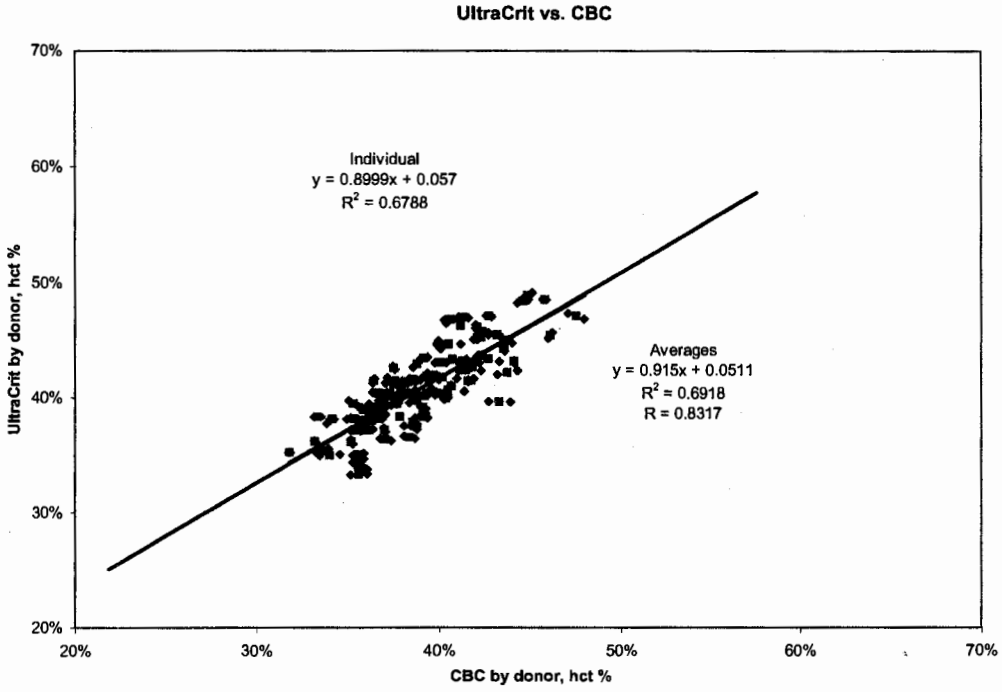
Regression Statistics		at 38% CBC	UC=37.60%
Multiple R	0.948994		
R Square	0.900591	95 % Lower Confidence Limit	37.43%
Adjusted R Square	0.900083		
Standard Error	0.011877	95 % Upper Confidence Limit	37.78%
Observations	198		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and CBC

Site 2, UC vs CBC, Individual Values

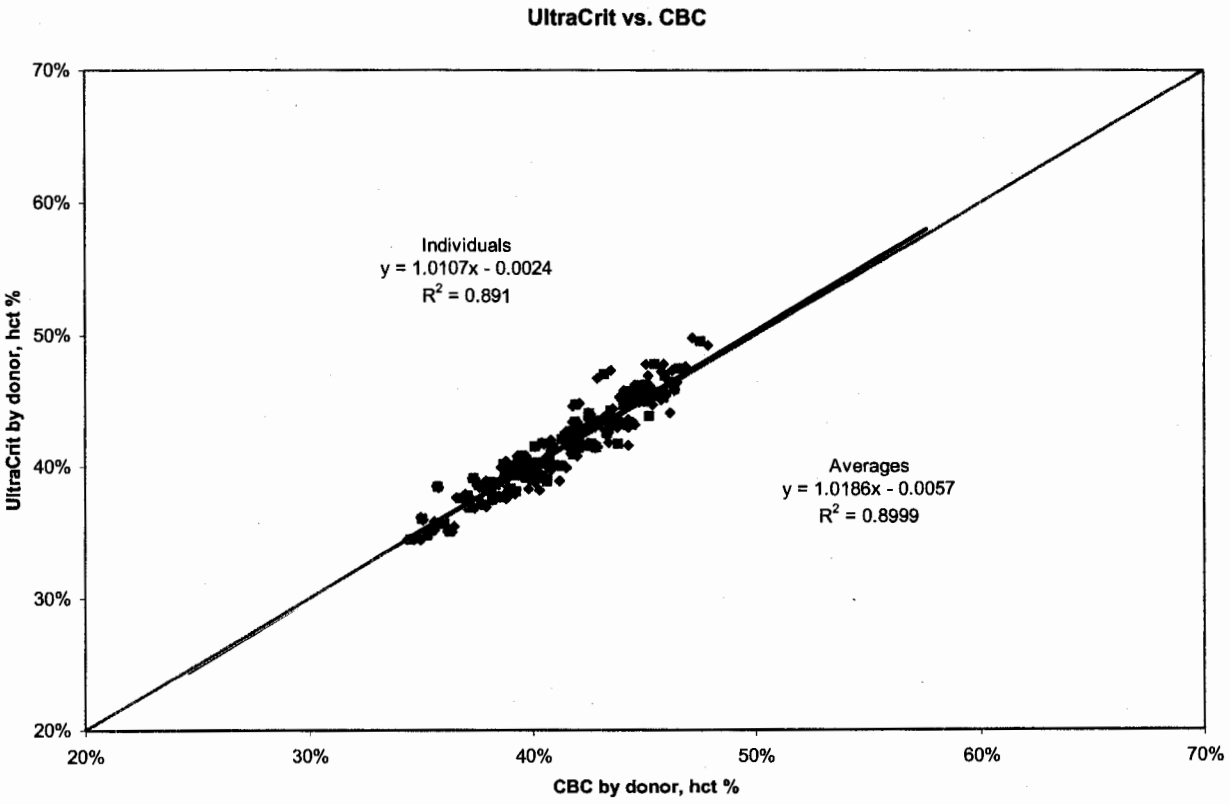
Regression Statistics		at 38% CBC	UC=39.90%
Multiple R	0.823884		
R Square	0.678785	95 % Lower Confidence Limit	39.53%
Adjusted R Square	0.677112		
Standard Error	0.019677	95 % Upper Confidence Limit	40.27%
Observations	194		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and CBC

Site 3, UC vs CBC, Individual Values

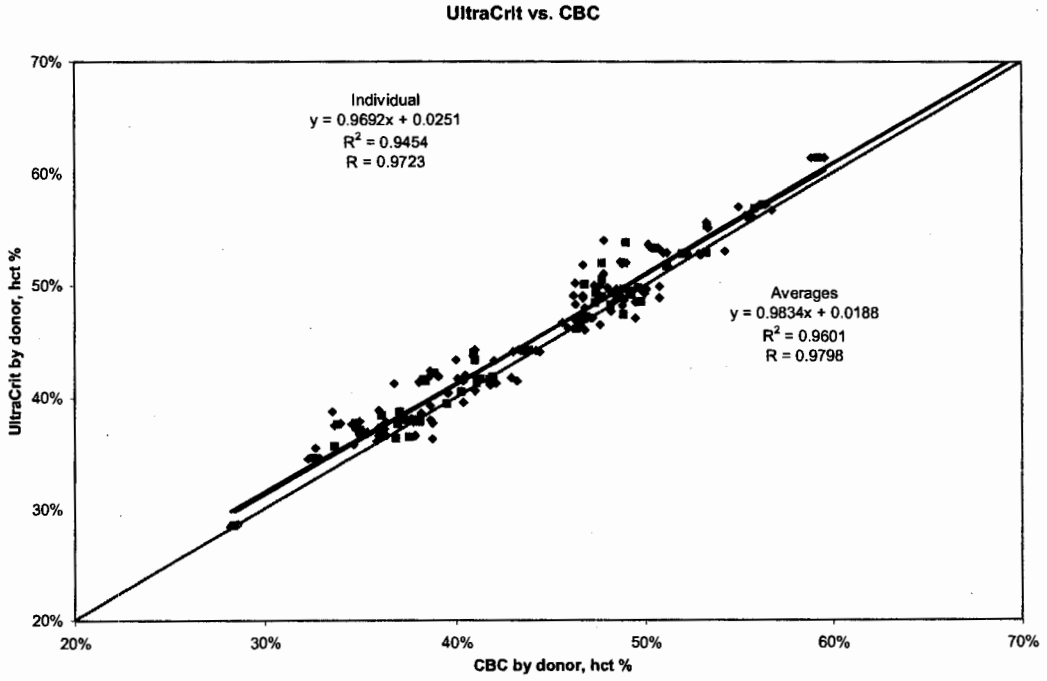
Regression Statistics		at 38% CBC	UC=38.16%
Multiple R	0.943936		
R Square	0.891015	95 % Lower Confidence Limit	38.01%
Adjusted R Square	0.890448		
Standard Error	0.010944	95 % Upper Confidence Limit	38.32%
Observations	194		



VENOUS BLOOD SITE STUDIES, SUMMARY, UltraCrit and CBC

Site 4, UC vs CBC, Individual Values

Regression Statistics		at 38% CBC	UC=39.34%
R	0.9723		
R squared	0.9454	95 % Lower Confidence Limit	39.03%
Adjusted R squared	0.9450		
Standard Error	0.0164	95 % Upper Confidence Limit	39.65%
Observations	120		



UltraCrit Reference Controls

Similarities			
Item	**Description**	**Predicate Device – HemataCHEK Controls** K924926	**UltraChek Reference Controls**
Intended Use/Test Objective	To monitor and evaluate the analytical performance of hematocrit measurements	Yes	Yes
Product Type	Hematology quality control material	Yes	Yes
Storage Temperature Range	15° - 30° C	Yes	Yes
Differences			
Item	**Description**	**Predicate Device – HemataCHEK Controls**	**UltraChek Reference Controls**
Materials	Determination of hematocrit	Red blood cell based fluid with preservative. Potential biohazard	Deionized and micro-filtrated water High Purity Grade NaCl FD&C Food Coloring
Performance	Operating Temperature range	15° - 30° C	10° - 40 ° C
Performance	Stability	2 years unopened 31 days opened	3 months (single use)
Performance	Low Precision	20.5 ± 0.95 (4.6% CV)	20.3 ± 0.17 (0.8% CV)
Performance	Normal Precision	41.9 ± 1.25 (3.0% CV)	40.2 ± 0.13 (0.7% CV)
Performance	High Precision	52.8 ± 1.80 (3.4% CV)	48.4 ± 0.17 (0.7% CV)

Discussion of differences between the UltraCrit devices and Predicate devices:

1) Operating Procedure:
   a. Determination of hematocrit – the UltraCrit sends an ultrasonic pulse through a sample of blood to make a determination of hematocrit while the predicate device uses centrifugal forces to separate the blood sample into its various constituents thus enabling the operator/user to make a visual assessment of the hematocrit value. While there are operating differences, they do not pose any additional safety related risk or reduction in effectiveness.
2) Methodology:
   a. The UltraCrit uses a different operational methodology, and the resulting information is more accurate and less prone to operator error (refer to results of studies provided earlier in this section).
3) Performance:
   a. Performance of the UltraCrit has been shown to be better than the HemataSTAT II (refer to results of performance studies provided earlier in this section).
4) Hematology Quality Controls:
   a. The hematology quality controls for the UltraCrit are no more difficult to use than the HemataSTAT II and pose fewer safety concerns because the quality control fluid for the UltraCrit is not a biohazard and is non-toxic.

Conclusion:

Based on the above information, we believe we have demonstrated that the similarities and technical differences between the UltraCrit device and control material and the HemataSTAT II device and control material do not raise any new safety concerns or effectiveness issues. Therefore, we believe the UltraCrit system meets the criteria for being substantially equivalent to the predicate devices.