DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 21, 2015

Mindray Bio-medical Electronics Co., LTD
c/o Jinjie Hu, Ph.D.
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington Street, Suite 100
Alexandria, VA 22314

Re: K143348
Trade/Device Name: BC-3600 Auto Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: August 10, 2015
Received: August 14, 2015

Dear Dr. Hu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BC-3600 Auto Hematology Analyzer

Indications for Use *(Describe)*
The BC-3600 auto hematology analyzer is a quantitative, automated hematology analyzer for in vitro diagnostic use in clinical laboratories. The BC-3600 auto hematology analyzer provide complete blood count (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV) and leukocyte 3-Part differential (Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%) for whole blood specimens, collected in a salt of EDTA [dipotassium (K2) or tripotassium (K3)] obtained by venipuncture or fingerstick. The purpose of the BC-3600 Auto Hematology Analyzer is to identify the normal human patient, with normal system-generated parameters, from patients whose results require additional studies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Mindray Bio-medical electronics co., LTD

BC-3600 Auto Hematology Analyzer

510(k) Premarket Notification

1. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the BC-3600 Auto Hematology Analyzer is provided below.

Device Common Name: Auto Hematology Analyzer

Device Proprietary Name: BC-3600 Auto Hematology Analyzer

Submitter: Mindray Bio-medical electronics co., LTD
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Date Prepared: November 14, 2014

Classification Regulation: 21 CFR 864.5220, Class II

Panel: Hematology

Product Code: GKZ

Predicate Device:

BC-3200 Hematology Analyzer (K093394) BC-3200 AUTO HEMATOLOGY ANALYZER, M-30D DILUENT, M-30R RINSE, M-30CFL LYSE, M-30E E-Z CLEANSER, M-30P PROBE CLEANSER, BC-3D, SC-CAL PLUS. SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

Indication for Use:

The BC-3600 auto hematology analyzer is a quantitative, automated hematology analyzer for in vitro diagnostic use in clinical laboratories. The BC-3600 auto hematology analyzer provide complete blood count (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV) and leukocyte 3-Part differential (Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%) for whole blood specimens, collected in a salt of EDTA [dipotassium (K_2) or tripotassium (K_3)] obtained by venipuncture or fingerstick.The purpose of the BC-3600 Auto Hematology Analyzer is to identify the normal human patient, with normal system-generated parameters, from patients whose results require additional studies.

Device Description

The BC-3600Auto Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. It is only to be used by trained medical professionals to identify the normal

patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies. The analyzer provides analysis results of 16 parameters of human blood and three histograms.

The BC-3600 Auto Hematology Analyzer system consists of:

- The analyzer (BC-3600)
- Reagents
  - M-30D DILUENT
  - M-30CFL LYSE
  - M-30R RINSE
  - PROBE CLEANSER
- Controls
  - BC-3D Control (High, Normal, Low levels)
- Calibrator
  - SC-CAL PLUS Calibrator

The analyzer provides analysis results of 16 parameters (listed below) of human blood and three histograms. The following list provides the abbreviations for all measurands:

Parameter	**Abbreviation**
White Blood Cell or leukocyte	WBC
Lymphocyte	Lymph#
Mid-sized cell	Mid#
Granulocyte	Gran#
Lymphocyte percentage	Lymph%
Mid-sized cell percentage	Mid%
Granulocyte percentage	Gran%
Red Blood Cell or erythrocyte	RBC
Hemoglobin Concentration	HGB
Hematocrit	HCT
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Cell (erythrocyte) Hemoglobin	MCH
Mean Cell (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte) Distribution Width	RDW
Platelet	PLT
Mean Platelet Volume	MPV

White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

Principle of Operation

WBCs are counted and sized by the impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell suspended in a conductive diluent as it passes through an aperture of known dimensions. HGB is determined by the colorimetric method. RBCs and PLTs are counted by the impedance method also. In addition, volumetric metering is used. An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count cycle is known. The analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed for the measurement.

Modes of Operation

The BC-3600 operates in a closed vial

Specimen identification

Specimen identification input is manual (by operator) or by barcode reader (optional).

Specimen sampling and handling

Samples are manually mixed and loaded into a sample compartment one at a time. The BC-3600 processes anti-coagulated whole blood collected in a K_2EDTA or K_3EDTA on two testing modes: whole blood analysis mode and predilute analysis mode.

Reagents, Calibrators and Controls

Reagents:

- M-30D DILUENT
- M-30R RINSE
- M-30CFL LYSE
- PROBE CLEANSER

Controls: BC-3D

Three levels of Controls with low, normal and high levels are provided. These Controls are exactly same as the Controls cleared in the predicate device BC-3200 analyzer. It is recommended to perform the quality control check using these controls at intervals established by the laboratory procedures and local or national regulations.

Calibrators: SC-CAL PLUS

Calibration and verification of Calibration are performed with the previously cleared Calibrator SC-CAL PLUS in the predicate device BC-3200 analyzer. The calibration and

quality control should be performed according to the instruction for the Calibrator and to laboratory procedures and local or national regulations.

Software

The software is used to operate the system which features sample management, sample processing, data acquisition, data processing, result management, patient data management, and instrument management. The system is comprised of the BC-3600 analyzer with touch screen.

The BC-3600 Auto Hematology Analyzer contains moderate risk level software which has been fully verified and validated and documentation in accordance with FDA Guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices: May 11, 2005" has been provided in this submission.

Special Control and Guidance Document Referenced

FDA Guidance	Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA	2001
H26-A2	Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard - Second Edition	2010
EP6-A	Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline	2003
H20-A2	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard - Second Edition	2007
EP09-A3	Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition	2014
EP17-A	Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline	2009
EP5-A2	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition	2005
C28-A3	Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline- Third Edition	2008

Performance Characteristics

Method comparison

A total of 1222 K_2EDTA whole blood samples were studied at three actual user sites, two in China and one in the US. Patients participated the study with age range from 1 day after birth to 100 years old, and with 547 females, 672 males and 3 samples with unknown age and gender. Patient's samples covered the normal and most abnormal

conditions for all parameters. For each whole blood sample, three manual wedge smears were prepared and stained with Wright-Giemsa stain. A 400 cell WBC differential was performed on two smears per CLSI H20-A2. All samples were testing on whole blood mode in parallel with BC-3600 analyzer and the predicate device. An estimation of the bias was determined for each parameter according to EP09-A3. The result demonstrated the BC-3600 analyzer met the pre-defined specification of the difference limits. Whole blood accuracy and regression vs predicate and the flagging ability of BC-3600 vs Manual differential comparison was performed. Table 1 shows that the combined results from three (3) sites are comparable to the predicate device.

Table 1: The Correlation and Estimated Bias of BC-3600 (Combined) (vs BC-3200)

Parameters	Result Range	r	slope (95%CI)	intercept (95%CI)	Mean	
					Predicate	Test
WBC (x 10^3/uL)	0.15 to 103.1	0.999	0.990 (0.988 to 0.992)	0.1861 (0.152 to 0.22)	11.29	11.36
Lymph# (x 10^3/uL)	0.1 ~ 12.45	0.985	1.0665 (1.057 ~ 1.076)	-0.155 (-0.176 ~ -0.134)	2.16	2.15
Mid# (x 10^3/uL)	0.05 ~ 2.75	0.873	1.101 (0.964~1.237)	-0.06537 (-0.12974~-0.001)	0.60	0.60
Gran# (x 10^3/uL)	0.1 ~ 47.65	0.998	1.0674 (1.064 ~ 1.071)	-0.2177 (-0.242 ~ -0.193)	5.96	6.15
Lymph% (%)	3.55 ~ 69.3	0.982	1.098 (1.088 ~ 1.108)	-3.2854 (-3.615 ~ -2.956)	30.67	30.39
Mid% (%)	2.25 ~ 14.85	0.677	0.577 (0.544~0.610)	3.2976 (3.031~3.564)	8.28	8.07
Gran% (%)	23 ~ 92.95	0.985	1.0462 (1.037 ~ 1.055)	-1.9542 (-2.524 ~ -1.385)	62.48	63.41
RBC (x 10^6/uL)	1.04 ~ 7.57	0.997	1.0098 (1.007 ~ 1.013)	-0.0296 (-0.043 ~ -0.016)	4.25	4.26
HGB (g/dL)	3.05 ~ 24.55	0.998	1.0055 (1.003 ~ 1.008)	-0.1434 (-0.178 ~ -0.109)	12.45	12.37
HCT (%)	9.6 ~ 73.75	0.997	0.9829 (0.98 ~ 0.986)	0.8568 (0.732 ~ 0.982)	38.03	38.23
MCV (fL)	50.7 ~ 124	0.994	1.0132 (1.009 ~ 1.018)	-0.875 (-1.27 ~ -0.48)	90.46	90.77
MCH (pg)	15.3 ~ 44.25	0.991	1.0087 (1.003 ~ 1.014)	-0.4767 (-0.641 ~ -0.312)	29.58	29.36
MCHC (d/fL)	25.15 ~ 47.65	0.915	0.943 (0.926~0.959)	1.4625 (0.922~2.003)	32.69	32.28
RDW (%)	11 ~ 20.7	0.901	1.1667 (1.1395~1.1892)	-2.4167 (-2.7514~-2.0523)	14.28	14.23
PLT (x 10^3/uL)	12 ~ 951.5	0.992	0.9847 (0.979 ~ 0.99)	7.0335 (5.453 ~ 8.614)	260.56	263.61

Parameters	Result Range	r	slope (95%CI)	intercept (95%CI)	Mean	
					Predicate	Test
MPV (fL)	6.3 ~ 11.8	0.865	0.793 (0.773~0.813)	1.6200 (1.452~1.788)	8.48	8.34

The WBC flagging rate for the BC-3600 was compared to the WBC manual differential for the same population of samples as shown in Table 2.

Table 2: The WBC Flagging Ability of BC-3600 (Combined) (vs Manual)

	BC-3600
True Positive	178
True Negative	739
False Positive	227
False Negative	64
Total	1208
Sensitivity (TP %)	73.6%
Specificity (TN %)	76.5%
Efficiency	75.9%

Precision/Reproducibility

Reproducibility study was performed on BC-3600 to evaluate the long term imprecision of the device using three level of control material (BC-3D control Low, Normal and High) for complete blood counts and leukocyte 3 Part Differential parameters. Each level control samples were run in duplicated twice each day for 20 days on the BC-3600 analyzer at each of the three clinical sites. Data were analyzed for each site and for the combined data from all sites used the same lot control according to the guidance provided in CLSI EP5-A2. For each site, the standard deviation (SD) and coefficient of variation (CV%) for within-run, between-run, between-day, and within-device were estimated. For the combined data from two clinical sites, the SD and CV% for within-run, between-run, between-day, between-device and total precision were calculated also. The reproducibility results in each site met the specifications.

Precision/Repeatability

To demonstrate the within-run precision as a coefficient of variation from replicates of a single sample, ten replicates of K_2EDTA whole blood samples around medical decision levels and the upper and lower limit of the analytical measuring range. Sample were selected and tested in the whole blood mode or the predilute mode at three clinical sites

respectively. The mean, standard deviation (SD), and coefficient of variation (CV) were calculated for each sample. All data in each site passed specifications.

Linearity Range

WBC and PLT high-value analogs, which come from commercialized materials, were diluted to different values respectively. RBC/HGB linearity was performed using dilutions prepared from fresh whole blood. The whole blood was concentrated to obtain specimens to test the high linearity limit. Serial dilutions were prepared using the diluent for each parameter to create 7 subsequent dilutions. The mean of multiple measurements, three (3), from each of the 7 dilutions across the linearity range were used. Acceptable performance is indicated by the data fitting a linear regression line with a coefficient of determination (R^2) of >0.95 and the parameters measured recovering within the bias limits for each parameters based on CLSI EP06-A.

Carryover

Carryover was determined for WBC, RBC, HGB and PLT. Testing was performed to test the different analytical cycle combinations of within mode for whole blood, within mode for predilute and mode to mode. For each analytical cycle combination, whole blood and predilute sample with extremely elevated blood components (high sample) and with decreased blood components (low sample) were tested in triplicates according to H26-A2.

For whole blood and predilute sampling, within mode and mode to mode for sampling carryover were calculated and the results were within specifications (≤ 0.5%) for WBC, RBC, HGB and (≤ 1.0%) for PLT. BC-3600 Analyzer demonstrated minimum carryover level within the defined specification for both Whole Blood and Predilute mode listed below.

Interference

The potential interfering substances of BC-3600 were found to be the same as the predicate BC-3200 analyzer due to the fact that the two devices had very similar principle. The interference studies of Bilirubin, Intralipid, and High WBC were performed for BC-3600 at one clinical site. The impact of those substances were analyzed and the results demonstrated that the elevated concentration of Bilirubin, Intralipid, or WBC in a sample will impact its measurement results on BC-3600.This exact same interference substances limitation can be found in predicate device BC-3200 (K093394).

Other Compatibility Studies

Comparison of Whole Blood Mode and Predilute Mode Sample

To demonstrate that BC-3600 analyzer performs equally on samples tested in different analysis modes, 61 pairs of samples representing the normal and medical conditions were

collected in K_2EDTA collection tube. All the samples were tested on BC-3600 analyzer with Whole blood mode and Predilute mode. The results were analyzed using StatisPro software according to CLSI EP09-A3 and showed that there was no difference when testing samples in either mode or when the sample contained parameters in normal or abnormal range due to medical conditions.

Comparison of Venipuncture and Fingerstick Sample

To demonstrate the comparable performance between capillary samples and the venous samples, 52 pair specimens were collected from donor by capillary method in K_2EDTA microtainer and venipuncture method in K_2EDTA collection tube. Specimen levels were selected to cover the analytical measuring interval and medical decision levels for each parameter. Each sample was tested in the whole blood mode at the U.S. site. The results were analyzed using StatisPro software according to CLSI EP09-A3 and showed that the performance characteristics of the two specimen types were comparable.

Comparison of K_2EDTA and K_3EDTA Anticoagulants Samples

To evaluate whether samples collected in K_2EDTA and K_3EDTA have the same performance characteristics on BC-3600 analyzer, 60 paired fresh whole blood samples collected in K_2EDTA and K_3EDTA anticoagulant tubes were tested. The samples were selected with the targets to cover the analytical measuring interval and medical decision levels for each parameter. Each sample is tested in whole blood mode on BC-3600 at actual user site in the U.S. The results were analyzed using StatisPro software according to CLSI EP09-A3 and showed that the performance characteristics of the specimens collected in the two anticoagulants are comparable.

Sample Stability

To test the time that the samples can be stored at certain conditions after collection and before testing without compromising the performance characteristic, whole blood and pre-dilute whole blood stability studies were performed with specimens collected in K_2EDTA anticoagulants. For the whole blood samples stability, a total of 35 normal and abnormal samples have been collected in the Finlay Laboratory (U.S. site) on BC-3600 analyzer. In addition, a total of 25 normal and abnormal samples have been collected in the NSH site for the predilute sample stability on BC-3600. Aliquots were prepared and stored at the defined condition for each specimen, then analyzed in duplicate at different time points according to the study design. When samples are stored for the durations defined at controlled room temperature [64-79° F (18-26° C)] or at refrigerated temperature [35.6-46.4° F (2-8° C)] the analyzer performance results met the acceptance limits according to CLSI EP25-A . The whole blood is stable for 24 hours at refrigerated temperature (2-8° C) and 12 hours when stored at 18-26° C for all parameters (except for the differential parameters Gran#/%, Mid#/%, Lymph#/% which are stable for 8 hours

when stored at 18-26° C). Predilute whole blood stability is 30 minutes when stored at 18-26° C after preparation and before testing for all parameters.

Reference Interval

A study was performed to assess the Adult Reference Ranges for BC-3600 analyzer using whole blood samples collected from 255 donors. In the study 124 adult male donors and 131 adult female donors between the ages of 19-85 were included. The non-parametric method and 95% confidence were used to calculate the lower and upper limits of the reference range according to C28-A3. The results are all shown in Table 3.

It is recommended that laboratories establish their own reference range based on the actual current patient population.

Table 3: The Reference Intervals of BC-3600

Parameters	Partitions	Male			Female			Combined		
	(Female vs Male)	N	Low Limit (90%CI)	Upper Limit (90%CI)	N	Low Limit (90%CI)	Upper Limit (90%CI)	N	Low Limit (90%CI)	Upper Limit (90%CI)
WBC	NO	125	4.12 (4.00~4.50)	12.27 (10.30~13.40)	131	4.23 (3.30~4.50)	13.21 (11.10~13.80)	256	4.20 (4.00~4.50)	12.36 (11.00~13.60)
Lymph#	YES*	125	1.00 (0.50~1.10)	3.70 (3.30~4.30)	131	0.89 (0.60~1.20)	5.14 (3.80~6.10)	256	1.00 (0.80~1.10)	4.16 (3.70~5.50)
Mid#	YES*	125	0.40 (0.30~0.40)	1.47 (1.10~2.00)	131	0.23 (0.20~0.30)	1.10 (1.00~1.20)	256	0.30 (0.20~0.40)	1.20 (1.10~1.50)
Gran#	NO	125	2.10 (1.80~2.20)	8.64 (7.50~8.90)	131	2.03 (1.80~2.20)	7.61 (7.10~10.00)	256	2.10 (2.00~2.20)	8.26 (7.10~8.80)
Lymph%	NO	125	14.83 (8.50~18.50)	45.40 (43.80~62.90)	131	15.72 (11.40~18.80)	50.75 (46.20~57.00)	256	14.89 (11.40~18.50)	47.52 (45.40~52.50)
Mid%	YES*	125	4.82 (4.40~5.70)	16.18 (12.60~30.50)	131	4.43 (4.20~4.60)	13.93 (12.30~14.90)	256	4.54 (4.40~4.80)	14.56 (12.60~16.30)
Gran%	NO	125	43.62 (31.10~46.50)	77.06 (74.80~82.40)	131	40.36 (36.40~44.10)	78.18 (74.00~83.00)	256	42.24 (37.80~45.50)	77.06 (74.70~80.90)
RBC	YES*	125	3.583 (3.320~3.830)	5.856 (5.600~6.410)	131	3.528 (3.300~3.730)	5.704 (5.340~6.430)	256	3.559 (3.370~3.770)	5.792 (5.590~6.410)
HGB	YES*	125	10.59 (9.80~11.90)	17.36 (16.90~18.00)	131	10.43 (10.10~11.00)	16.04 (15.60~16.20)	256	10.50 (10.20~11.30)	16.90 (16.70~17.40)
HCT	YES*	125	33.74 (30.00~35.60)	50.90 (50.20~52.40)	131	33.60 (31.10~34.30)	47.42 (46.10~48.40)	256	33.60 (31.90~34.60)	50.32 (48.60~50.90)
MCV	NO	125	77.13 (64.90~82.90)	100.91 (99.40~103.00)	131	71.28 (66.40~81.30)	99.91 (97.70~101.10)	256	75.67 (69.70~81.30)	100.09 (98.60~101.10)
MCH	NO	125	24.75 (20.50~27.50)	33.87 (33.10~35.10)	131	22.14 (20.70~26.40)	33.47 (32.60~34.10)	256	23.73 (21.70~26.70)	33.56 (33.10~34.10)
MCHC	YES*	125	31.52 (31.20~32.20)	34.90 (34.80~35.60)	131	31.03 (30.00~31.60)	34.50 (34.40~36.10)	256	31.24 (31.00~31.80)	34.90 (34.80~35.20)
RDW	NO	125	11.80 (11.40~11.90)	15.83 (14.70~17.20)	131	11.53 (11.40~11.80)	15.22 (14.60~17.50)	256	11.64 (11.40~11.80)	15.40 (14.80~16.60)
PLT	YES*	125	145.0 (79.0~168.0)	368.7 (361.0~515.0)	131	159.0 (111.0~169.0)	456.6 (415.0~565.0)	256	157.3 (136.0~167.0)	435.5 (401.0~515.0)
MPV	NO	125	6.72 (6.50~7.00)	9.60 (9.30~9.90)	131	6.90 (6.40~7.10)	10.01 (9.50~11.20)	256	6.84 (6.60~7.00)	9.80 (9.50~10.10)

YES*: denoted that a separate reference interval should be considered for the partitions of Male and Female.

Determination of Limit of Blank (LoB), Limits of Detection (LoD) and Limit of Quantitation (LoQ)

Limit of Blank was determined using five blank samples (diluent) which just contain the predilute solution. To determine the Limits of Detection and Limit of Quantitation, five low levels of samples were created by adding whole blood samples to dilutent to reach approximately 4 times of the LoB. Each blank sample or low level sample is tested for 12 times at one clinical laboratory in China tested in the whole blood mode on three BC-3600 analyzer and the low level samples are tested for 5 times on BC-3200 analyzer. The results were analyzed according to CLSI EP17-A. The LoB on the BC-3600 for WBC is 0 x 10^3/uL, PLT is 2.1 x 10^3/uL. The LoB and LoD on the BC-3600 for WBC is 0.05 x 10^3/uL, PLT is 3.4 x 10^3/uL.

Substantial Equivalence

Table 4 and Table 5 summarize the similarities and differences between the BC-3600 Hematology and the predicate device.

Table 4: Device Comparison Table - Similarities

Similarities		
Item	BC-3600	Predicate BC-3200
Intended Use	The BC-3600 auto hematology analyzer is a quantitative, automated hematology analyzer for in vitro diagnostic use in clinical laboratories. The BC-3600 auto hematology analyzer provide complete blood count (WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV) and leukocyte 3-Part differential (Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%) for whole blood specimens, collected in a salt of EDTA [dipotassium (K_2) or tripotassium (K_3)] obtained by venipuncture or fingerstick.The purpose of the BC-3600 Auto Hematology Analyzer is to identify the normal human patient, with normal system-generated parameters, from patients whose results require additional studies.	The BC-3200 auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter to be used in clinical laboratories for In Vitro Diagnostic purpose. The intended use of BC-3200 Auto Hematology Analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

Similarities		
Test Principle	WBC, RBC, MCV, RDW, PLT and MPV: Coulter principle of Impedance method HGB: Colorimetric method WBC Differential: Instrument calculates a three population leukocyte count (Lymph%, Mid%, Gran%) from the WBC histogram based on cell size determined by impedance method. The absolute number for each population is then calculated.	Same
Sample Type	Whole blood	Same
Sampling Mechanism	Manual presentation for closed vial sampling whole blood analysis and pre-dilute analysis mode	Same
Sample Processing	Utilizes an automatic sampling, diluting and mixing device for sample processing	same
Sample ID	Manual barcode scan of sample tube identifier or manual keyboard entry of sample identifier	Same
Parameters	Parameters(16): WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV	Same
Data Analysis	Analyze analog raw data to generate reported parameters	Same
Data Reporting	Display, printing and transmission of data to LIS/HIS.	Same
System Throughput	60 samples per hour	Same (1 minute / analysis)
Software Risk Level	Moderate	Same
Mode of Operation	Whole Blood Closed Vial Analysis Mode Pre-dilute Analysis Mode	Same
Analysis Reagents	M-30D DILUENT M-30CFL LYSE M-30R RINSE	Same
Controls	BC-3D Controls – 3 Levels	Same
Calibrators	SC-CAL PLUS Calibrator	Same

Similarities		
Analysis Mode	Whole Blood Mode and Pre-dilute Mode	Same
Quality Control Techniques	L-J Analysis and X-B Analysis	Same
Sample Preparation	Syringe for sample aspiration / delivery and also for reagent delivery	Same

Table 5: Device Comparison Table - Differences

Differences		
Item	BC-3600	Predicate BC-3200
Sample Anticoagulant	K_2EDTA or K_3EDTA	K_2EDTA only
Cleaning Agents	PROBE CLEANSER	M-30P PROBE CLEANSER M-30E E-Z CLEANSER
Sample Aspiration Volume	21 µL of whole blood in whole blood analysis mode 20µL of blood to prepare a pre-diluted sample for the Pre-dilute analysis mode	13 µL of whole blood in the whole blood analysis mode 20µL of blood to prepare a pre-diluted sample for the Pre-dilute analysis mode
Display	TFT Color Touch Screen, 800×600 pixels	Color LCD, 10.4'', 800x600 pixels
I/O Interfaces	- One LAN interface, built-in network card, TCP/IP compatible - One RS-232 port to support the host connected to LIS with serial port - 4 USB ports	- One keyboard interface - Two RS-232 interfaces - One parallel port - One power supply for the floppy disk drive

Substantial Equivalence Conclusion

The BC-3600 Auto Hematology Analyzer has the exact same intended use as the predicate device, the BC-3200 as cleared in K093394. Both the BC-3600 Auto Hematology Analyzer and the predicate use the same technology as a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. These analyzers may be used in adult and pediatric population. Both analyzers are only to be used by trained medical professionals to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies. The analyzer provides analysis

results of 16 parameters of human blood and three histograms. The minor differences are tested for their performance impact. The results demonstrated that they do not impact substantial equivalence.