510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k093394

B. Purpose for Submission:
To obtain clearance for unmasking of 4 previously shielded parameters of a cleared device (k063407)

C. Manufacturer and Instrument Name:
Shenzhen Mindray Bio-Medical Electronics Co., Ltd
BC-3200 Auto Hematology Analyzer

D. Type of Test or Tests Performed:
WBC, Lymph #, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, MCV, MCH, MCHC, RDW, HCT, MPV, WBC Histogram, RBC Histogram, and PLT Histogram

E. System Descriptions:
1. Device Description:
The BC-3200 Auto Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential cell counter for In Vitro Diagnostic use in clinical laboratories. It consists of the analyzer, M-30 serial reagents (M-30D diluent, M-30CFL lyse, M-30R rinse, M-30E E-Z cleanser and M-30P probe cleanser), SC-CAL plus calibrators and BC-3D controls.
The BC-3200 Auto Hematology Analyzer 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 parameter of human blood and three histograms.

2. Principles 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, for RBCs and PLTs, 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.

3. Modes of Operation:
Closed Vial Whole Blood Mode, Whole Blood Mode for venous blood, and Predilute Mode for capillary blood.

4. Specimen Identification:
Barcode or manual keyboard entry.
5. Specimen Sampling and Handling:
Samples are manually loaded into a sample compartment one at a time. The BC-3200 utilizes an automatic sampling and mixing device for sample processing. The Mindray calibrator is called SC-CAL PLUS.

6. Calibration:
The device has two calibration programs: manual calibration and auto calibration using commercial calibrators. The Mindray calibrator is called SC-CAL PLUS.

7. Quality Control:
The device has two QC programs: L-J Analysis and X-B Analysis. The Mindray three level control is called BC-3D)

8. Software:
All components of the device are controlled/monitored by software, which is responsible for the functionality, user interface, safety checks and performance accuracy.
FDA has reviewed applicant’s Hazard Analysis and Software Development processes for this line of product types:
Yes ___ X ___ or No _______

F. Regulatory Information:
1. Regulation section:
21 CFR §864.5220: Automated Differential Cell Counter
2. Classification:
Class II
3 Product code:
GKZ: Counter, Differential Cell
4. Panel:
81 Hematology

G. Intended Use:
1. Indication(s) for Use:
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.
2. Special Conditions for Use Statement(s):
N/A

H. Substantial Equivalence Information:
1. Predicate Device Name(s) and 510(k) numbers:
COULTER® AC•T diff 2™ Analyzer, k990352
2. Comparison with Predicate Device:
### Similarities

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>A quantitative, automated hematology analyzer and leukocyte differential counter for <em>In Vitro</em> Diagnostic Use in clinical laboratories</td>
<td>Same</td>
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<tr>
<td>Sample Types</td>
<td>Whole Blood Mode and Prediluted Mode</td>
<td>Same</td>
</tr>
<tr>
<td>Sample Processing</td>
<td>Utilizes an automatic sampling, diluting, and mixing device for sample processing</td>
<td>Same</td>
</tr>
<tr>
<td>Calibration</td>
<td>2 calibration programs: manual calibration and auto calibration using commercial calibrators</td>
<td>Same</td>
</tr>
<tr>
<td>Aperture Alert</td>
<td>Minimize the possibility of reporting erroneous results caused by a partial or transient aperture clog or by other aperture disturbance</td>
<td>Same</td>
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<tr>
<td>Display</td>
<td>LCD</td>
<td>Same</td>
</tr>
</tbody>
</table>

### Differences

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Modes</td>
<td>Closed Vial Whole Blood Mode</td>
<td>Closed Vial Whole Blood Mode and Open Vial Whole Blood Mode</td>
</tr>
<tr>
<td>Throughput</td>
<td>1 minute/analysis</td>
<td>60 seconds or less for each sample</td>
</tr>
<tr>
<td>Quality Control</td>
<td>2 QC programs: L-J Analysis and X-B Analysis</td>
<td>1 QC program: L-J Analysis</td>
</tr>
<tr>
<td>Recommended Controls</td>
<td>BC-3D: Low, Normal, &amp; High</td>
<td>4C PLUS: Abnormal Low, Normal, Abnormal</td>
</tr>
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### Differences

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended Calibrator</td>
<td>CBC-CAL PLUS</td>
<td>S-CAL calibrator</td>
</tr>
<tr>
<td>Sample Volume Aspirated</td>
<td>13 μL whole blood</td>
<td>18 μL whole blood</td>
</tr>
<tr>
<td></td>
<td>20 μL prediluted blood</td>
<td>20 μL prediluted blood</td>
</tr>
<tr>
<td>Reagents Required</td>
<td>M-30D Diluent</td>
<td>diff A&lt;sup&gt;C-T&lt;/sup&gt; Park or diff A&lt;sup&gt;C-T&lt;/sup&gt; Tain reagent park, both of which contain diluent and lytic reagent. A&lt;sup&gt;C-T&lt;/sup&gt; Rinse Shutdown Diluent</td>
</tr>
<tr>
<td></td>
<td>M-30R Rinse</td>
<td></td>
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<tr>
<td></td>
<td>M-30CFL Lyse</td>
<td></td>
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<tr>
<td></td>
<td>M-30E E-Z Cleanser</td>
<td></td>
</tr>
<tr>
<td></td>
<td>M-30P Probe Cleanser</td>
<td></td>
</tr>
<tr>
<td>Parameters</td>
<td>WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph%, Lymph#, Mid%, Mid#, Gran%, Gran#, RDW, MPV</td>
<td>WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Ly%, Ly#, MO%, MO#, GR%, GR#, RDW, MPV</td>
</tr>
<tr>
<td>WBC Operating Range</td>
<td>0.0 - 299.9 (×10&lt;sup&gt;3&lt;/sup&gt;/μL)</td>
<td>0.0 - 150 (×10&lt;sup&gt;3&lt;/sup&gt;/μL)</td>
</tr>
<tr>
<td>RBC Operating Range</td>
<td>0.00 - 19.99 (×10&lt;sup&gt;6&lt;/sup&gt;/μL)</td>
<td>0.00 - 8.00 (×10&lt;sup&gt;6&lt;/sup&gt;/μL)</td>
</tr>
<tr>
<td>HGB Operating Range</td>
<td>0 - 29.9 (×g/dL)</td>
<td>0.00 - 30.0 (×g/dL)</td>
</tr>
<tr>
<td>PLT Operating Range</td>
<td>0 - 2999 (×10&lt;sup&gt;3&lt;/sup&gt;/μL)</td>
<td>000 - 3000 (×10&lt;sup&gt;3&lt;/sup&gt;/μL)</td>
</tr>
<tr>
<td>MCV Operating Range</td>
<td>0.0 - 249.9 fL</td>
<td>50.0 - 130.0 fL</td>
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### I. Special Control/Guidance Document Referenced (if applicable):


J. Performance Characteristics:
1. Analytical Performance:
   a. Accuracy:
      Established under k063407
   b. Precision/Reproducibility:
      Established under k063407
   c. Linearity:
      Established under k063407
   d. Carryover:
      Established under k063407
   e. Interfering Substances:
      The sponsor provided a list of commonly known interferences as supported by published references.

2. Other Supportive Instrument Performance Data Not Covered Above:
   a. Software Documentation:
      Modifications of the software that allow the sponsor to add the four parameters (i.e., Mid%, Mid#, RDW, MPV) to previously claimed 12 parameters for the BC-3D control and to add them at the QC screen have been sufficiently documented.
      The sponsor has provided acceptable documentation demonstrating that the sponsor developed software for this device under an appropriate software development program; performed hazard analyses from both the patient's and user's standpoints, and addressed those hazards; and carried out an appropriate validation process. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way.

K. Proposed Labeling:
   The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:
   The submitted information in this premarket notification is complete and supports a substantial equivalence decision.