**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**

**A. 510(k) Number:**

K182078

**B. Purpose for Submission:**

New device

**C. Measurand:**

Not applicable - blood collection system

**D. Type of Test:**

Not applicable

**E. Applicant:**

Greiner Bio-One North America Inc.

**F. Proprietary and Established Names:**

MiniCollect® K2E K2EDTA Tubes

**G. Regulatory Information:**

1. Regulation section:

   21 CFR 862.1675 (Blood specimen collection devices)

2. Classification:

   Class II

3. Product code:

   JKA (Tubes, Vials, Systems, Serum Separators, Blood Collection)

4. Panel:

   Hematology (81)

## H. Intended Use:

1. Intended use(s):

   MiniCollect® K2E K2EDTA Tubes are non-evacuated blood collection devices, used to collect, transport, store, and evaluate capillary blood specimens for the following hematology parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, Platelets, RDW, Lymphocytes, Neutrophils, Monocytes, Eosinophils and Basophils.

2. Indication(s) for use:

   Same as Intended Use.

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Specific analyzers used to evaluate the device are listed in the labeling and described in the Section M2a (Method Comparison) below.

   The device is to be used by trained healthcare professionals in accordance with the instructions for use.

## I. Device Description:

MiniCollect Tubes are plastic, non-evacuated, non-sterile low sample volume tubes with integrated collection devices. The closure (cap) is color coded to identify the additives which are present in varying concentrations depending on the tube type and stated volumes. The closure (cap) of the MiniCollect tube is lavender in color.

The interior of the tube wall is coated with dipotassium EDTA (K2EDTA).

Two product versions are available: MiniCollect Tubes with optional 13x75 mm carrier tubes (clear, amber), and MiniCollect Complete, pre-assembled with 13x75 mm carrier tubes.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   BD Microtainer® MAP Microtube for Automated Process

2. Predicate 510(k) number(s):
   K093972

3. Comparison with predicate:

| Similarities and Differences | | |
|---|---|---|
| Item | Device<br>MiniCollect K2E K2EDTA Tubes | Predicate<br>BD Microtainer MAP Microtube for Automated Process (K093972) |
| Intended Use | MiniCollect® K2E K2EDTA Tubes are non-evacuated blood collection devices, used to collect, transport, store, and evaluate capillary blood specimens for the following hematology parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, Platelets, RDW, Lymphocytes, Neutrophils, Monocytes, Eosinophils and Basophils. | BD Microtainer® MAP Microtube for Automated Process with K2EDT A is used to collect, anticoagulate, transport and store skin puncture blood specimens for measurements of the following hematological parameters: White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HgB), Hematocrit (HCT), Mean corpuscular volume (MCV), Mean corpuscular Hemoglobin (MCH), Mean Corpuscular hemoglobin concentration (MCHC), Platelets, 5 -part White Blood Cells (WBC) differentials (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils), Reticulocytes and Whole Blood Lead testing. |
| Tube Dimension | 13 x 75mm | Same |
| Draw Volume | 0.25–0.5 ml | Same |
| Closure | Cap with pierceable membrane | BD Microgard closure |
| Closure Color | Lavender | Same |
| Closure material(s) | Polyethylene (PE)-rigid component and Thermoplastic Elastomer (TPE)-soft component) | Plastic |
| Collection tube feature/material | With integrated collection scoop/Polypropylene (PP) | With integrated collection scoop/plastic |
| Carrier/Extender Tube | Polyethylene Terephthalate (PET) | Plastic |

| Similarities and Differences | | |
|---|---|---|
| Item | Device<br>MiniCollect K2E K2EDTA Tubes | Predicate<br>BD Microtainer MAP Microtube for Automated Process (K093972) |
| Anticoagulant | $K_2$EDTA (Ethylenediaminetetraacetic Acid Dipotassium Dihydrate) | Same |
| Interior Coating of Additive | Spray-coated and dried | Same |
| Storage Condition | 4–25 °C | <25°C |
| Shelf Life | 534 days | 540 days |
| Sterility and Use | Non-sterile and single use only | Same |

**K. Standard/Guidance Document Referenced (if applicable):**

- CLSI GP42-A6: Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition
- CLSI GP39-A6: Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard - Sixth Edition
- CLSI GP34-A: Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline
- CLSI EP09-A3: Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition
- CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP25-A - Evaluation of Stability of in Vitro Diagnostic Reagents; Approved Guideline
- ISO 6710:2017 Single-use containers for venous blood specimen collection

**L. Test Principle:**

The MiniCollect K2E K2EDTA Tubes are plastic, non-evacuated, non-sterile low sample volume collection devices. The interior of the tube wall is coated with $K_2$EDTA which binds calcium ions thus blocking the coagulation cascade. Sample draw volume is 0.25-0.5 ml collected via capillary (finger or heel stick) using a lancet and filling the tube or venous via syringe and transferred to the tube.

**M. Performance Characteristics (if/when applicable):**

1. <u>Analytical performance:</u>

   *a. Precision/Reproducibility:*

   The precision study was performed on venous blood collections including within-

tube, between-run, as well as between-lot precision testing at one site (University of Maryland). The collected blood was transferred to a total of eight tubes (five evaluation tubes from three lots and three control tubes) via syringe. The following parameters were tested: WBC, RBC, HGB, HCT, PLT. For the MiniCollect K2EDTA tubes, mixed models were fit to estimate the variability within the tube while controlling for different subjects. Estimates of the SD and %CV were computed for the evaluation tubes and compared to the acceptance criteria. Further, the relative SD of the test and control tubes were also compared to see if 1 was included in the confidence interval.

The Repeatability/Reproducibility evaluations were conducted in accordance with CLSI EP5-A3 and CLSI GP34-A standards and the results are shown in the tables below:

| Repeatability | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Parameter | Mean | SD | | | %CV | | | | Relative SD | |
| | | Min | Max | Mean | Min | Max | Mean | 95% CI | Mean | 95% CI |
| WBC | 5.778 | 0.000 | 0.240 | 0.096 | 0.000 | 4.597 | 1.669 | (1.303, 2.322) | 0.892 | (0.509, 1.562) |
| RBC | 4.575 | 0.000 | 0.071 | 0.031 | 0.000 | 1.886 | 0.685 | (0.535, 0.953) | 0.789 | (0.450, 1.382) |
| HGB | 13.31 | 0.000 | 0.212 | 0.072 | 0.000 | 1.677 | 0.542 | (0.423, 0.754) | 0.795 | (0.454, 1.393) |
| HCT | 39.75 | 0.000 | 0.636 | 0.293 | 0.000 | 2.036 | 0.736 | (0.575, 1.024) | 0.924 | (0.527, 1.619) |
| PLT | 255.2 | 0.000 | 10.61 | 4.968 | 0.000 | 4.810 | 1.947 | (1.520, 2.709) | 0.950 | (0.542, 1.664) |

| Between- Run Reproducibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Parameter | Mean | SD | | | CV% | | | |
| | | Min | Max | Mean | Min | Max | Mean | 95% CI |
| WBC | 5.901 | 0.000 | 0.474 | 0.215 | 0.000 | 9.276 | 3.642 | (2.900, 4.898) |
| RBC | 4.404 | 0.000 | 0.240 | 0.118 | 0.000 | 6.228 | 2.682 | (2.136, 3.606) |
| HGB | 12.81 | 0.000 | 0.495 | 0.212 | 0.000 | 4.250 | 1.651 | (1.315, 2.220) |
| HCT | 39.03 | 0.000 | 2.828 | 1.484 | 0.000 | 8.421 | 3.804 | (3.029, 5.117) |
| PLT | 233.9 | 0.000 | 15.56 | 7.628 | 0.000 | 7.039 | 3.261 | (2.597, 4.386) |

| Between-Lot Reproducibility | | | | | | |
|---|---|---|---|---|---|---|
| | Parameter Range | | | SD | CV% | |
| Parameter | Mean | Min | Max | Mean | Mean | 95% CI |
| WBC | 5.872 | 2.940 | 10.21 | 0.035 | 0.602 | (0.314, 3.787) |
| RBC | 4.357 | 2.230 | 6.400 | 0.000 | 0.000 | (0.000, 0.000) |
| HGB | 12.78 | 7.100 | 17.10 | 0.000 | 0.000 | (0.000, 0.000) |

| Between-Lot Reproducibility | | | | | | |
|---|---|---|---|---|---|---|
| | Parameter Range | | | SD | CV% | |
| Parameter | Mean | Min | Max | Mean | Mean | 95% CI |
| HCT | 38.31 | 23.30 | 49.60 | 0.000 | 0.000 | (0.000, 0.000) |
| PLT | 236.9 | 51.00 | 384.0 | 0.000 | 0.000 | (0.000, 0.000) |

| Variance Components | | | | | |
|---|---|---|---|---|---|
| Parameter | WBC | RBC | HGB | HCT | Platelets |
| N | 166 | 166 | 166 | 166 | 165 |
| Mean | 5.87 | 4.44 | 12.96 | 39.04 | 241.97 |
| Min | 2.88 | 2.18 | 7.10 | 23.00 | 51.00 |
| Max | 10.21 | 6.64 | 17.10 | 53.40 | 384.00 |
| Repeatability SD | 0.10 | 0.03 | 0.07 | 0.30 | 5.11 |
| Repeatability CV | 1.68 | 0.73 | 0.57 | 0.76 | 2.19 |
| Between-run SD | 0.12 | 0.06 | 0.13 | 0.58 | 4.36 |
| Between-run CV | 2.08 | 1.34 | 1.03 | 1.48 | 1.87 |
| Within-lot SD | 0.16 | 0.07 | 0.15 | 0.65 | 6.72 |
| Within-lot CV | 2.67 | 1.52 | 1.18 | 1.67 | 2.87 |
| Between-lot SD | 0.04 | 0.00 | 0.00 | 0.00 | 0.00 |
| Between-lot CV | 0.70 | 0.00 | 0.00 | 0.00 | 0.00 |
| Within-Device | 0.16 | 0.07 | 0.15 | 0.65 | 6.72 |
| Within-Device | 2.76 | 1.52 | 1.18 | 1.67 | 2.87 |

*b. Linearity/assay reportable range:*

Not applicable.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Per the instructions for use of the MiniCollect K2E K2EDTA Tubes, the user should refer to the instrument labeling for sample stability.

*d. Detection limit:*

Not applicable.

*e. Analytical specificity:*

Not applicable.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

To demonstrate that the evaluation tube (MiniCollect K2E K2EDTA Tube) is substantially equivalent to the predicate device (BD Microtainer K2EDTA Tube) a method comparison study was conducted consisting of blood specimens collected from both adult and pediatric donors using the Coulter DxH 800 (K081930), Sysmex XE-5000 (K071967), and Cell-Dyn Sapphire (K051215) hematology analyzers. Capillary, venous and heel stick samples had one measurement for each parameter on the evaluation tube and on the predicate/control tube. Weighted Deming regression was performed for each analyte and the percent difference (%CV) and the difference in values (Abs) were presented.

Outliers were removed using the extreme studentized deviated test where up to 5% of the paired samples were allowed to be removed if there appeared to be outliers.

| **Method Comparison - All Instruments Regression Summary** | | | | |
|---|---|---|---|---|
| **Parameter** | **N** | **Slope (95% CI)** | **Intercept (95% CI)** | **Correlation (r) (95% CI)** |
| BAS | 440 | 1.015 (0.778, 1.253) | -0.002 (-0.009, 0.005) | 0.7020 |
| EOS | 422 | 1.051 (1.016, 1.086) | -0.005 (-0.009, -0.000) | 0.9857 |
| HCT | 436 | 1.001 (0.995, 1.008) | -0.025 (-0.259, 0.209) | 0.9928 |
| HGB | 436 | 1.000 (0.995, 1.004) | 0.015 (-0.036, 0.067) | 0.9942 |
| LYM | 431 | 1.010 (0.995, 1.026) | -0.016 (-0.043, 0.011) | 0.9872 |
| MCH | 439 | 1.004 (0.995, 1.013) | -0.106 (-0.356, 0.144) | 0.9940 |
| MCHC | 438 | 0.995 (0.964, 1.027) | 0.158 (-0.882, 1.199) | 0.9547 |
| MCV | 445 | 1.004 (0.999, 1.009) | -0.281 (-0.726, 0.163) | 0.9986 |
| MON | 434 | 0.993 (0.953, 1.032) | 0.008 (-0.011, 0.028) | 0.9618 |
| NEU | 427 | 1.001 (0.990, 1.011) | -0.002 (-0.048, 0.043) | 0.9961 |

| | | | | |
|---|---|---|---|---|
| PLT | 436 | 1.008 (0.998, 1.019) | 0.805 (-1.180, 2.790) | 0.9834 |
| RBC | 436 | 0.998 (0.992, 1.003) | 0.010 (-0.011, 0.032) | 0.9923 |
| RDW | 441 | 1.001 (0.993, 1.009) | -0.009 (-0.115, 0.098) | 0.9973 |
| WBC | 446 | 0.998 (0.988, 1.008) | 0.024 (-0.040, 0.088) | 0.9930 |

*b. Matrix comparison:*

To demonstrate that there is no significant difference in the test results obtained using capillary specimens as compared to venous specimens a matrix comparison study was conducted consisting of blood specimens collected from adult donors only using the Coulter DxH 800 and Sysmex XE-500 hematology analyzers. Each subject had one capillary sample measurement and one venous sample measurement from each tube type for each parameter. The following parameters were tested using venous and capillary blood specimens: WBC, RBC, HGB, HCT, MCV, MCV, MCH, MCHC, Platelets, RDW, Lymphocytes, Neutrophils, Monocytes, Eosinophils, Basophils. Three clinical sites (Beckman Coulter DxH 800; Sysmex XE-5000; Beckman Coulter DxH 800/Sysmex XE-5000) participated in the evaluation. For the MiniCollect K2EDTA Tubes, Deming regression was performed for each analyte to account for error in both venous and capillary measurement. The estimates and 95% confidence intervals for the bias are expressed in terms of the percent and absolute difference. Depending on the parameter, up to three medical decision points were included in the analysis of the bias. The medical decision points used in the analysis of each parameter were included as levels in the performance results. Then appropriate measure was compared to the acceptance criteria

| Matrix Comparison - All Instruments Regression Summary | | | | |
|---|---|---|---|---|
| **Parameter** | **N** | **Slope (95% CI)** | **Intercept (95% CI)** | **Correlation (r)** |
| BAS | 246 | 0.960 (0.548, 1.372) | -0.009 (-0.026, 0.008) | 0.5784 |
| EOS | 241 | 0.927 (0.891, 0.964) | 0.003 (-0.002, 0.008) | 0.9842 |
| HCT | 242 | 0.982 (0.948, 1.016) | 0.484 (-0.827, 1.795) | 0.9691 |
| HGB | 241 | 0.962 (0.929, 0.994) | 0.346 (-0.067, 0.760) | 0.9749 |
| LYM | 244 | 0.972 (0.939, 1.006) | -0.017 (-0.077, 0.043) | 0.9699 |
| MCH | 244 | 0.996 (0.984, 1.008) | 0.089 (-0.257, 0.435) | 0.9943 |
| MCHC | 244 | 0.934 (0.889, 0.979) | 2.001 (0.503, 3.498) | 0.9325 |
| MCV | 244 | 1.026 (1.017, 1.034) | -1.789 (-2.486, -1.092) | 0.9971 |
| MON | 248 | 0.946 (0.883, 1.009) | 0.009 (-0.023, 0.042) | 0.9370 |

| | | | | |
|---|---|---|---|---|
| NEU | 240 | 0.964 (0.947, 0.982) | -0.001 (-0.066, 0.064) | 0.9919 |
| PLT | 237 | 0.993 (0.928, 1.059) | 11.587 (-2 .804, 25.977) | 0.9364 |
| RBC | 244 | 0.955 (0.918, 0.993) | 0.150 (-0.015, 0.315) | 0.9683 |
| ROW | 243 | 1.001 (0.982, 1.019) | 0.005 (-0.248, 0.258) | 0.9964 |
| WBC | 243 | 0.959 (0.931, 0.987) | 0.013 (-0.191, 0.218) | 0.9850 |

3. Clinical studies:

   *a. Clinical Sensitivity:*

   Not Applicable.

   *b. Clinical specificity**:***

   Not Applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

   *Fill Accuracy Study:*

   Fill accuracy study was conducted to demonstrate conformity to CLSI GP39-A6 regarding +/- 10% of fill volume accuracy of the MiniCollect tubes. Testing was done according to standard ISO 6710 Annex A because CLSI GP39-A6 does not define a testing procedure for fill accuracy testing. When tested in accordance with the methods as specified, the volume of water should be within ±10 % of the draw volume. All tested parts fulfilled the draw volume test and have fill accuracy inside the tolerance limits. All tested MiniCollect tube results were within specifications and in accordance with requirement of +/-10% fill accuracy according to CLSI GP39-A6.

   *Transportation Stress Test:*

   Transport stress test was conducted to demonstrate that there is no significant effect of temperature and humidity on MiniCollect tubes when the tubes are shipped by various transport methods internationally and domestically. The samples used in the clinical study at the U.S. sites were transported by airfreight and truck shipment. The device was exposed to low temperatures during international and domestic flights in the plane freight room. The device was also exposed to elevated temperatures during the summer months (27–34°C) and reflect extreme changes in temperature and humidity during the various transport methods.

4. Clinical cut-off**:**

Not Applicable.

5. Expected values/Reference range:

Not Applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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