January 25, 2019

Greiner Bio-One NA Inc.
Manfred Abel
Quality System & Regulatory Affairs Manager
4238 Capital Drive
Monroe, North Carolina 28110

Re: K182078
Trade/Device Name: MiniCollect K2E K2EDTA Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 1, 2018
Received: August 2, 2018

Dear Manfred Abel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182078

Device Name
MiniCollect® K2E K2EDTA Tubes

Indications for Use *(Describe)*
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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5. PREMARKET NOTIFICATION 510(K)SUMMARY

1. SUBMITTER

Applicant Name: Greiner Bio-One GmbH
Bad Haller Strasse 32
4550 Kremsmuenster,
Austria

Contact person: Manfred Abel, M.S., MBA
Greiner Bio-One NA Inc.
4238 Capital Drive
Monroe, NC 28110
704 261 7823
Manfred.Abel@gbo.com

Establishment registration number: 8020040

Date prepared: Jan 24, 2019

2. DEVICE

Trade Name: MiniCollect® K2E K2EDTA Tubes

Common name: Blood Collection Tubes

Classification:

Name:	Tubes, Vials, System, Serum Separator, Blood Collection
Product Code:	JKA
Regulation No:	862.1675
Class:	II
Regulation Medical Specialty:	Clinical Chemistry
510k Review Panel:	Hematology

3. PREDICATE DEVICE

BD Microtainer® MAP Microtube for Automated Process (K093972)

4. DEVICE DESCRIPTION

MiniCollect® Tubes are plastic, non-evacuated, non-sterile low sample volume tubes with integrated collection devices. The closure is color-coded to identify the additives which are present in varying concentrations depending on the tube type and stated volumes. The caps of the MiniCollect® Tubes are pierceable for automated instruments with cap-piercing functionalities.

The interior of the tube wall is coated with dipotassium EDTA (K2EDTA). The EDTA binds calcium ions thus blocking the coagulation cascade.

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

The product is to be used by appropriately trained healthcare professionals in accordance with these instructions.

5. INDICATION FOR 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Evaluation Device **MiniCollect® K2E K2EDTA Tubes**	**Predicate Device** **BD Microtainer® MAP Microtube for Automated Process**
FDA Status	Under Review	K093972
Classification	Class II	Class II
Regulation	862.1675	862.1675
Classification Product Code	JKA	JKA
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 K_2EDTA 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.
Manufacturer	Greiner Bio-One (GBO)	Becton Dickinson & Company.

Device characteristics All data as detailed as known:		
	Evaluation Device **MiniCollect® K2E K2EDTA Tubes**	**Predicate device** **BD Microtainer® MAP Microtube for Automated Process**
Tube Dimension	13 x 75mm	13 x 75mm
Draw Volume	0.25 – 0.5 mL	0.25 - 0.5 mL
Closure	Cap with pierceable membrane	BD Microgard closure
Closure Color	Lavender	Lavender
Closure material(s)	PE (rigid component), TPE (soft component)	Plastic
Collection tube feature / material	With integrated collection scoop / PP	With integrated collection scoop / plastic
Carrier/Extender Tube	PET	Plastic
Storage Condition	4 -25 °C	<25°C
Anticoagulant	K2EDTA (Ethylenediaminetetraacetic Acid Dipotassium Dihydrate)	K2EDTA (Ethylenediaminetetraacetic Acid Dipotassium Dihydrate)
Interior Coating of Additive	Spray-coated and dried	Spray-coated and dried
Shelf Life	534 days	540 days
Use	Single use only	Single use only
Tube sterility	Non-sterile	Non-sterile

Packaging Configuration, Materials and Dimensions All data as detailed as known:		
Rack / shelf pack quantity / material	50 MiniCollect® tubes or MiniCollect® Complete, Polystyrene black	50 BD Microtainer® MAP Microtube tubes
Case quantity / material	10 racks (500 tubes) MiniCollect® tubes / corrugated board	N/A
Case quantity / material	10 racks (500 13x75mm tubes) MiniCollect® Complete / corrugated board	4 shelf packs (200 BD Microtainer® MAP Microtube tubes)
Master case / material	4 cases (2000 MiniCollect® tubes or MiniCollect® Complete) / corrugated board	N/A

As above comparison table shows the evaluation device and the predicate device have the same fundamental technology and technological characteristics. The intended use of the MiniCollect® K2E K2EDTA Tubes is similar to the predicate device. Both devices are intended to collect, transport, store and evaluate capillary blood specimens for hematology tests. The used materials are the same or at least comparable in regards to safety and effectiveness of the device. Based on the intended use, device features, principles of operation, and technological characteristics we believe MiniCollect® K2E K2EDTA Tubes are substantially equivalent to the predicate device.

7. PERFORMANCE DATA

A. Performance Testing - Bench

The MiniCollect® K2E K2EDTA Tubes are manufactured and tested in conformity to a variety of standards, internal specifications and in comparison to the predicate device.

Requirement	Based on:	Pass/Fail
Durability of the container during centrifugation	ISO 6710 and GP39-A6	Pass
No leakage of container	ISO 6710 and GP39-A6	Pass
Closure Resealing	GP39-A6 and internal test protocol spp0284	Pass
Transport stability	ASTM D4169	Pass

B. Performance Testing – Clinical

The performance evaluation of the MiniCollect® K2EDTA Tubes was based on applicable standards, guidance documents, statistical evaluation and accepted medical decision points. The study was conducted at three external clinical sites. Clinical performance testing was performed to demonstrate that blood specimens collected in Greiner Bio-One MiniCollect® K2EDTA blood collection tubes produced test results are substantially equivalent to the predicate tube by performing the following studies: Method Comparison, Precision Repeatability and Reproducibility and Stability. Results were evaluated in accordance with the associated Statistical Analysis Plan for MiniCollect® K2EDTA Tubes. Data generated from the studies were compared to the acceptance criteria for the Evaluation Tube and Control Tube.

The following abbreviations for the parameters are used.

Parameter	Abbreviation
WBC (White blood cells)	WBC
RBC (Red blood cells)	RBC
HGB (Hemoglobin)	HGB
HCT (Hematocrit)	HCT
MCV (Mean cellular volume)	MCV
MCH (Mean cellular hemoglobin)	MCH
MCHC (Mean cellular hemoglobin concentration)	MCHC
Platelets	PLT
RDW (Red blood cell distribution width)	RDW
Lymphocytes	LYM
Neutrophils	NEU
Monocytes	MON
Eosinophils	EOS
Basophils	BAS

Method Comparison,

2 Method Comparison

The purpose of the method comparison with the predicate device was to demonstrate that the evaluation tube (MiniCollect® K2EDTA Tube) is substantially equivalent to the control tube (BD Microtainer® K2EDTA Tube). The method comparison consisted of blood specimens collected from both adult and pediatric donors. Capillary, venous and heel stick samples had one measurement for each parameter on the evaluation tube and on the control tube. For the MiniCollect® K2EDTA Tubes, Deming regression was performed for each analyte to account for error in both evaluation and control tube measurements. The estimates and 95% confidence intervals for the bias were expressed in terms of the percent difference (CV%) and the difference in values (Abs).
Comparison testing was performed on the following hematology analytes: WBC, RBC, HGB, HCT, MCV, MCV, MCH, MCHC, Platelets, RDW, Lymphocytes, Neutrophils, Monocytes, Eosinophils, Basophils to meet the substantial equivalence requirements.

As per the CLSI EP09, the bias criteria were met at all medical decision points for all parameters. The regression line criteria were not met in two cases (BAS, EOS) across the data for all sites. One case was for Basophils where the correlation (r) was below the acceptance criteria. The values for Basophils are typically in the range of 0.00-0.10, but can only be measured to the nearest 0.01 at 2 sites or to the nearest 0.1 at one site. This causes the differences to be either 0 or at least as large as the rounding error. These differences can be relatively large and cause the correlation coefficient to be small. This also causes the 95% CI for the slope to be wide and not be contained in the interval 0.9 - 1.1. The other regression line that did not meet the acceptance criteria was for Eosinophils. The 95% CI for the y-intercept did not include 0, but was so close, that the upper limit is reported as -0.000 due to rounding. In each of these cases, the statistical deviations were minor and did not lead to deviations in the estimated bias of the analytes.

Overall, each parameter passed the acceptance criteria for bias and there does not appear to be a difference in the measurement of any parameter values between evaluation and control tubes

Precision Repeatability and Reproducibility

The purpose of the study was to demonstrate the precision of assay results including repeatability and reproducibility. The study was performed on venous blood collections including within-tube, between-run, as well as between-lot precision testing. 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 below.

Parameter	Acceptance Criteria
WBC	15%
RBC	6%
HGB	7%
HCT	6%
PLT	25%

Repeatability Study Conclusion

The repeatability, of the representative hematology parameters tested on 26 donors collected in MiniCollect® K2EDTA tubes showed acceptable variation compared to the predicate tubes.

Reproducibility (between-lot) Study Conclusion

The aim of the study was to evaluate any variation on 30 donors in the measurements generated from blood collected in multiple lots of the evaluation tube, tested on a single instrument under the same conditions, to demonstrate reproducibility of the test results obtained. The results generated in this study show acceptable between-lot variability, and therefore demonstrate between-lot reproducibility for the representative hematology results obtained from specimens collected in the MiniCollect® K2EDTA tubes.

Variance Component Analysis Conclusion

The aim of the analysis was to evaluate any variation in the representative hematological results generated with specimens collected in MiniCollect® K2EDTA tubes compared to the predicate tubes. The analysis demonstrates an acceptable level of variability.

Stability

The purpose of the study was to evaluate the equivalence of hematology results in specimens collected in MiniCollect® K2EDTA Tubes and in control tubes when the specimens were stored at room temperature. Evaluation tubes using blood samples collection from 25 adult donors were tested at three-time points, i.e. time zero (t_0), 12 hours post collection, and 15 hours post collection.

Parameter	Acceptance Criteria
WBC	15%
RBC	6%
HGB	7%
HCT	6%

MCV	2.3%
MCH	2.7%
MCHC	2.2%
Platelets	25%
RDW	4.6%
Lymphocytes	16%
Neutrophils	22.4%
Monocytes	27.9%
Eosinophils	37.1%
Basophils	38.5%

All evaluation tubes (25/25) met stability acceptance criteria for WBC, RBC, HGB, HCT, MCH, PLT, LYM and NEU at 12 and 15 hours. For the evaluation tubes, stability acceptance criteria were met in 24/25 samples at 12 and 15 hours for MON and in 23/25 samples at 12 and 15 hours for EOS. For RDW, 20/25 and 13/25 samples met the acceptance criterion at 12 and 15 hours, respectively. The acceptance criterion was met in 18/25 samples at 12 hours and in 21/25 samples at 15 hours for BAS. For MCHC, 16/25 tubes met the criterion at 12 hours and 5/25 met the criterion at 15 hours. Lastly, 15/25 tubes met the criterion at 12 hours and 0/25 met the criterion at 15 hours for MCV.

8. Discussion / Conclusion

The comparison between the evaluation device and the predicate device shows that they have the same fundamental technology and technological characteristics. The intended use of the MiniCollect® K2E K2EDTA Tubes is equivalent to the predicate device and the used materials are the same or at least comparable in regards to safety and effectiveness of the device.

The performance bench testing based on applicable standards and internal specifications demonstrates that acceptance criteria were met.

The evaluation device, MiniCollect® K2EDTA Tube was compared to the predicate device, when blood collected in each tube was analyzed for representative hematology parameters. The results generated in the clinical performance testing for method comparison, for precision and for stability demonstrate equivalent performance.

9. Substantial equivalency

The submitted information in this premarket notification shows that MiniCollect® K2E K2EDTA Tubes is comparable to the predicate device in design, function and intended use and meets established performance criteria. Therefore, MiniCollect® K2E K2EDTA Tubes is substantially equivalent to the predicate device.