BK210621 - Traditional 510(k) Summary
(In accordance with 21 CFR §807.92)

A. Applicant

Company Name:	NanoEntek, Inc.
Address:	851-14 Seohae-ro, Paltan-myeon, Hwaseong-si, Gyeonggi-do, 18531, Korea.
Contact Person:	Jason Jeong
Phone Number:	+82-2-6220-7887
Facsimile Number:	+82-2-6220-7980

B. Contact Person

Address:	(b) (6)
Contact Person:	Donna Cole
Title:	Consultant

C. Date Prepared: July 30, 2021

D. Trade name: r-Control RBC and PLT

Classification name: Hematology quality control mixture

Classification: 21 CFR §864.8625, Product code MZG, Class II

E. Predicate device: R&D Systems, R&D LeukoReduced RBC Control (BK000035) and R&D LeukoReduced PLT Control (BK000036)

F. Indications for Use:

The r-Control RBC High and Low is intended as a complete process control to monitor the process of dilution, staining and enumeration of residual leukocytes in leukocyte reduced RBC products to be used with the ADAM-rWBC Kit on the ADAM-rWBC Instrument. For *in vitro* diagnostic use only.

The r-Control PLT High and Low is intended as a complete process control to monitor the process of dilution, staining and enumeration of residual leukocytes in leukocyte reduced PLT products to be used with the ADAM-rWBC Kit on the ADAM-rWBC Instrument. For *in vitro* diagnostic use only

Device Description

It is an established laboratory procedure to use stable control to monitor the performance of the diagnostic tests. The r-Control is a stable material that provides a mean of monitoring the performance of methods that measure residual leukocytes in blood products using the

ADAM-rWBC Kit. It is sampled in the same manner as blood products used for transfusion purposes.

G. Substantial Equivalence Discussion

An overview of the similarities and differences between NanoEntek r-Control RBC and PLT and R&D LeukoReduced RBC and PLT controls, is provided in the table below.

Comparison with Predicate

	NanoEntek **r-Control RBC, r-Control PLT**	**R&D Systems** **BK000035, BK000036** **R&D LeukoReduced RBC Control** **R&D LeukoReduced PLT Control**
Intended use	**r-Control RBC** The r-Control RBC High and Low is intended as a complete process control to monitor the process of dilution, staining and enumeration of residual leukocytes in leukocyte reduced RBC products to be used with the ADAM-rWBC Kit on the ADAM-rWBC Instrument. For *in vitro* diagnostic use only. **r-Control PLT** The r-Control PLT High and Low is intended as a complete process control to monitor the process of dilution, staining and enumeration of residual leukocytes in leukocyte reduced PLT products to be used with the ADAM-rWBC Kit on the ADAM-rWBC Instrument. For *in vitro* diagnostic use only.	**R&D System LeukoReduced RBC Control** R&D LeukoReduced RBC Control is used to monitor methods for enumeration of residual leukocytes in leukoreduced red blood cell products, including the dilution and staining process, method setup and WBC enumeration. **R&D Systems LeukoReduced PLT Control** R&D Systems LeukoReduced PLT Control is used to monitor methods of enumeration of residual leukocytes in leukoreduced platelet products, including the dilution and staining process, method setup and WBC enumeration.
Used with the ADAM-rWBC System	Yes	Yes

Composition of reagents	**r-Control RBC** The r-Control RBC is an *in vitro* diagnostic reagent composed of mammalian erythrocytes and human leukocytes in a plasma-like fluid with preservatives. **r-Control PLT** The r-Control PLT is an *in vitro* diagnostic reagent composed of mammalian platelets and human leukocytes in a plasma-like fluid with preservatives.	**LeukoReduced RBC Control** LeukoReduced RBC is an *in vitro* diagnostic reagent composed of mammalian erythrocytes and human leukocytes suspended in a plasma like-fluid with preservatives. **LeukoReduced PLT Control** LeukoReduced PLT is an *in vitro* diagnostic reagent composed of mammalian platelets and human leukocytes suspended in a plasma like-fluid with preservatives.
Usage per test	100 µL	100 µL
Open vial stability	30 days	30 days or 21 thermal cycles (uses)
Closed vial stability	75 days	75 days
Storage temperature	2°C~8°C	2°C~8°C
Packaging/Components/ Volume	2.5 ml in each vial of RBC High, RBC Low, PLT High, PLT Low	3.0 ml in each vial of RBC High, RBC Low PLT High, PLT Low

H. Summary of Performance Characteristics:

The following performance data is provided in support of the substantial equivalence determination. All testing was conducted on the ADAM-rWBC Instrument per Instruction Manual, using the ADAM-rWBC Kit per the Package Insert.

1. Analytical Performance

a. *Precision/Reproducibility*

Precision Repeatability: Performed at NanoEntek Laboratory in Korea. Three lots, 2 control levels of r-Control material (Low and High), 2 replicates, 2 runs per day for 20 days were assessed for repeatability, between days, and run to run. Acceptance criteria is %CV (b) (4) in the low concentration, %CV (b) (4) in the high concentration, and within the allowable range for tested control.

Reproducibility: Multi-site testing was performed at NanoEntek Laboratory Korea and 2 USA laboratories. One lot, 2 levels of r-Control material (Low and High), 3 replicates, 5 runs per day, for 5 days were assessed for repeatability, between-days, between-runs, between-sites, and reproducibility. Acceptance criteria is %CV (b) (4) in the low concentration, %CV (b) (4) in the high concentration, and within the allowable range for tested control.

b. *Linearity/assay reportable range*:
Not applicable.

c. *Traceability, Stability, Expected values:*

Value Assignment: The Value Assignment established the allowable range and was performed at NanoEntek Laboratory. Assessed were 3 lots, 2 levels of control material (Low and High) for r-Control and R&D LeukoReduced control, with 2 replicates, 2 runs per day for 5 days. The allowable range is based on the confidence level and final assay assignment values are determined using the data collected and established product performance characteristics.

Vial Stability: Performed and assessed at NanoEntek Laboratory using 3 lots of 2 levels of control material (Low and High).

1. *Open vial stability*: 30 day open vial stability claim.
2. *Closed vial stability*: 75 day closed vial stability claim.
3. *Environmental Conditions:* Before mixing the r-Control material for use, a standing time of 15 minutes at room temperature (18~30ºC) is required after removing the vial from refrigerated storage (2~8ºC. Protect from freezing, temperatures above 30ºC, and prolonged time at room temperature (18ºC~30ºC).

d. *Limit of Detection*:
Not applicable

e. *Analytical Specificity*:
Not Applicable

f. *Assay Cut-off:*
Not Applicable

2. Comparison Studies

a. *Method comparison with predicate device*:
Not applicable

b. *Matrix comparison*:

Summary of Comparison Between Human and (b) (4) Matrix: The NanoEntek controls are manufactured from human and mammalian (b) (4) matrices. This testing ensures that the (b) (4) matrix is the same as an actual sample of human blood.

Testing was performed at NanoEntek Laboratory in Korea. Human and (b) (4) RBC and PLT matrices, prepared by injection of the same number of WBCs in the source matrix of testing,

were assessed using the ADAM-rWBC Instrument. For each matrix, two concentrations (low~2 WBCs µL; high ~20 WBCs µL), 2 replicates, 5 runs were analyzed.
Acceptance criteria is Recovery relative to (b) (4) cells/µL: (b) (4) cells/µL; (b) (4) cells/µL: (b) (4) where reference values are no matrix.

3. Clinical Studies:
Not applicable

4. Expected values/reference ranges:

The mean and expected assay values provided for each parameter are derived from replicate analyses. Assay values are determined on well-maintained, properly calibrated ADAM-rWBC Instruments using the ADAM-rWBC Kit. Reagent differences, maintenance, operating technique, and calibration may contribute to inter-laboratory variation.
Upon receipt of a new r-Control lot, it is recommended that assay values be confirmed before the new lot is put into use. For greater control sensitivity, each laboratory should establish its own mean and acceptable range and may include values outside of the assay range.

I. Labeling

The labeling complies with 21 CFR§809.10. Symbols used in labeling comply with ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

J. Compliance with standards and guidelines

- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Procedure; Approved Guideline-Third Edition
- CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition
- CLSI EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
- CLSI EP15-A2, User Verification of Performance for Precision and Trueness; Approved Guideline
- CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard

K. Conclusion

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