Traditional 510(k) Summary
(in accordance with 21 CFR §807.92)

A. Applicant

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B. Contact Person

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C. Date Prepared: September 10, 2020

D. Trade name: ADAM-rWBC HT System
Classification name: Automated Differential Cell Counter
Classification Panel: Hematology
CFR and Product code: 21 CFR §862.5220, Product code GKZ,
Classification: Class II

E. Predicate device: ADAM-rWBC System (BK120015; BK120068)

F. Indications for Use

The ADAM-rWBC HT system is intended for in vitro use for the enumeration of residual white blood cells (rWBCs) in leukoreduced blood products.

G. Device Description

The ADAM-rWBC HT System consists of the following components:

- ADAM-rWBC HT ("high throughput" or "HT") automated microscopic cell counting device.
- ADAM-rWBC HT Trays (5) for testing samples, calibrator and Quality Control samples
- ADAM-rWBC HT PC and software for operation (LCD monitor used for setup, initiation of testing, displaying the result, managing the data)
- ADAM-rWBC Kit which includes:
    - r-Solution

- Standard Bead Solution
- Bulk packaged r-Slides

- Hands free bench top Barcode Scanner that is interfaced with the instrument to allow scanning of the sample number and the r-Slide barcode (which includes the year, production number and serial number)

The principle and testing technology of the ADAM-rWBC HT and ADAM-rWBC (predicate) systems are the same. The ADAM-rWBC HT instrument uses the same microfluid chip technology; the same LED fluorescence microscope system and encased detector; is designed for counting residual white blood cells (rWBCs) in leukoreduced blood products (RBCs and platelets) by measuring stained nuclei from disrupted cells treated with lysing agent and Propidium Iodide. The main differences are that the ADAM-rWBC HT instrument is an automated, high throughput device which has an integral robotic sample loader so that multiple samples can be loaded and tested at one time, allowing the user to "walk away" and perform other tasks, and this system includes a PC and software for operation.

H. Substantial Equivalence Discussion

An overview of the similarities and differences between the ADAMI-rWBC HT System and ADAM-rWBC System (predicate) is provided in the Tables 1 – 3 below.

Table 1 General

	ADAM-rWBC System BK120015; BK120068	ADAM-rWBC HT System
Indications for Use	The ADAM-**rWBC** system is intended for *in vitro* use for the enumeration of residual white blood cells (rWBCs) in leukoreduced blood products.	The ADAM-**rWBC HT** system is intended for *in vitro* use for the enumeration of residual white blood cells (rWBCs) in leukoreduced blood products.
Principle Method/Technology	Microfluid chip technology Nucleic acid dye (Propidium Iodide) for leukocyte staining Fluorescence microscope system and encased detector Enumeration of residual WBCs	

Table 2 Instrument/software

	ADAM-rWBC instrument BK120015; BK120068	ADAM-rWBC HT instrument
Description	**Single** microchannel chip inserted **manually** into cell counter and scanned optically using a green LED (532 nm)	**Multiple** single microchannel chips loaded and **automatically, sequentially inserted** into cell counter and scanned optically using a green LED (532 nm) Integrated Magazine
Trays	No	Yes
Camera	1/3" CCD	½" CMOS
Measuring volume/r-Slide	57µL	
Analysis time per test	2.5 ~3 minutes	~1 minute
Results display	On instrument	On PC
Scanner	No	Yes
Software for:		

	Set up, test start/stop	On instrument	On PC
	Counting progress shows		
	Check operation and status		
	Data management	No	Yes On PC
	Controller	In instrument Image analysis software Analysis (cell count per µL) displayed on instrument	In instrument Image analysis software Analysis (count per µL) displayed on PC Robotics Control
Power supply		Power cord and SMPS	

Table 3 Reagent Kits and Sample

	ADAM-rWBC Kit for ADAM-rWBC BK120015; BK120068	ADAM-rWBC Kit For ADAM-rWBC HT
Sample type	RBC's; platelets	
Kit components	r-Solution	
	Standard Bead Solution	
	Single packaged r-Slides	Bulk packaged r-Slides designed for use with the ADAM-rWBC HT instrument
Measuring range	1 – 100 cells/µL	
Testing sample measuring volume	57 µL	
Sample stability	24 hours	
Stain sample stability	1 hour	
Interfering conditions (lipid; hemoglobin)	None	
Quality Control materials	Same	
Standard Bead solution	Same	

I. Summary of Performance Data:

Internal verification testing of the ADAM-rWBC HT System was conducted at the NanoEntek laboratory in Seoul, Korea, using NanoEntek staff (and where appropriate, as compared to the ADAM-rWBC).

1. Linearity

Linear and polynomial fit models were used and demonstrated linearity of 1-100 cells/µL.

- RBCs: $R^2 = 0.992$; R^2 adjusted = 0.992
- Platelets: $R^2 = 0.993$; R^2 adjusted = 0.993

2. Method Comparison – Accuracy

300 CPDA-1 RBC and 300 CPDA-1 Platelet clinical samples per three (3) operator/instrument were tested (N=900 total for each sample type). Target concentrations:

- <5 WBC/µL: RBC N = 379; platelet N = 318
- ≥5 WBC/µL: RBC N = 521; platelet N = 582

R^2, Slope, and Intercept; Bias Compared to Predicate

	N	R^2	Slope (95% CI)	Intercept (95% CI)
RBC				
rWBC cells/µL	900	1.00	0.99 (0.99-1.00)	0.040 (-0.009- 0.068)
Platelet				
rWBC cells/µL	900	1.00	0.98 (0.97-0.99)	0.025 (-0.005- 0.075)

Bias	N	Parameter	Estimate	95% CI	SE
RBC					
WBC (<5 cells/uL)	379	Mean difference	0.016	-0.0440 to 0.0754	0.0304
WBC (≥5 cells/uL)	521	Mean relative difference	-1.94%	-2.626% to -1.256%	0.349%
Platelet					
WBC (<5 cells/uL)	318	Mean difference	0.1008	0.03183 to 0.16986	0.03508
WBC (≥5 cells/uL)	582	Mean relative difference	1.89%	1.102% to 2.677%	0.401%

3. Preliminary Precision

Preliminary precision was conducted internally by 3 operators/instruments, using clinical samples, 50 replicates per concentration, run twice per day (2 hours between runs), for 2 days.

RBC

Sample	Mean value	N	Repeatability		Between Day		Between Run		Between instrument		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
5-10	7.94	600	0.94	11.81%	0.12	1.50%	0.00	0.00%	0.48	6.00%	1.06	13.34%
20-30	21.39	600	1.68	7.87%	0.00	0.00%	0.00	0.00%	0.57	2.70%	1.78	8.31%
50-60	52.15	600	2.65	5.09%	0.00	0.00%	0.00	0.00%	2.11	4.00%	3.39	6.50%
80-100	97.02	600	4.21	4.34%	0.59	0.60%	0.00	0.00%	2.69%	2.80%	5.03	5.19%

Platelet

Sample	Mean value	N	Repeatability		Between Day		Between Run		Between instrument		Reproducibility	
			SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV
5-10	8.14	600	0.81	9.95%	0.00	0.00%	0.00	0.00%	0.15	1.90%	0.82	10.12%
20-30	21.02	600	1.41	6.71%	0.00	0.00%	0.00	0.00%	0.67	3.20%	1.56	7.43%
50-60	54.35	600	2.36	4.35%	0.00	0.00%	0.00	0.00%	1.89	3.50%	3.02	5.56%
80-100	100.08	600	3.80	3.80%	0.73	0.70%	0.00	0.00%	1.45%	1.40%	4.14	4.13%

4. Interfering substances

Testing for hemolysis and lipemia was conducted. Testing demonstrated no difference in the effect of high levels of lipids (~3000 mg/dL) or hemoglobin (~1500 mg/dL).

5. Summary of bulk packaged r-Slide stability

Real time testing of bulk packaged r-Slide stability was assessed and determined to be:

- Unopened storage at 0-30^{0}C: 24 months
- Opened storage at 0-30^{0}C: 6 months

J. Proposed 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, labelling and information to be supplied – Part 1: General requirements.

K. Compliance with standards and guidelines

Electrical

- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- FCC CFR 47 Part 15 Subpart B, Section 15.101
- EN 61010-1:2010, AMD1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
    - EN 61010 61010-1:2010, AMD1:2019 more recent compared to FDA recognized IEC 61010-1 Edition 3.1, 2017-01
- IEC/EN 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Software

- Guidance for Industry and FDA Staff; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Content of Premarket Submission for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, October 2, 2014 (Draft guidance, October 18, 2018)
- Postmarket Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, December 28, 2016
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, Guidance for Industry and Food and Drug Administration Staff, September 6, 2017

- ANSI/AAMI/IEC 62304:2006/A1:2016 Medical devices software – Software life cycle
- EN ISO 14971:2019 Medical devices- Application of risk management to medical devices
- IEC 61010-1:2010 E3.1 2017-01 Safety requirements for electrical equipment for measurement, control, and laboratory use- Part 1: General requirements

Performance Testing

- CLSI-EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline
- CLSI-EP07-A3, Interference Testing in Clinical Chemistry
- CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods
- CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition

Labelling

- ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.

L. Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence determination when compared to the predicate device. The ADAM-rWBC HT System will perform as expected.