SECTION 6 – BK210625 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

1. Company:

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2. Device Name:

Device Trade Name:	IH-500
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated System for Blood Grouping and Antibody Test System
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Regulatory Class:	Class II

3. Identification of Legally Marketed Device (Predicate Device):

Device Trade Name:	IH-500
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated System for Blood Grouping and Antibody Test System
510(k) Number	BK180274
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Regulatory Class:	Class II
Clearance Letter	March 19, 2019

4. Description of the Device:

The IH-500 automated process includes sample identification, automated recording of reagents (lot numbers, expiration dates), sample dilutions, reagent addition and mixing, incubation and centrifugation, image acquisition and analysis. Through data management software (IH-Com), it is possible to compile and transmit information to an existing Laboratory Information System (LIS).

The IH-500 Analyzer is used for the following tests:

- ABO+RhD Blood Grouping, including Reverse Grouping and weak D testing
- Rh phenotyping (C, c, E, e) and Kell blood grouping (K)
- Antibody screening and identification
- Direct Antiglobulin Testing (DAT)
- AHG Crossmatch
- Antibody Titration Testing

The IH-500 analyzer system consists of the following primary components:

- IH-500 analyzer
- Integrated touch screen monitor with keyboard
- IH-Com software
- Computer
- Hand-held barcode reader
- Printer
- Smartcard reader for user identification

5. Intended Use:

The IH-500 is an automated instrument intended for the in vitro serological analysis for blood grouping and antibody detection of human blood specimens. The IH-500 automates pipetting of samples and reagents, incubation and centrifugation, and provides reaction grading / interpretation based on results from gel card images. Analysis includes ABO, Rh(D) (including weak D and partial D testing), Rh Phenotype and Kell blood grouping, antibody screening and identification of red blood cell alloantibodies, crossmatch, auto control, direct antiglobulin testing and antibody titration testing.

In the USA, IH-500 is “Rx only”. The IH-500 may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-500 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. Use of IH-500 is only permitted with gel cards and reagents from the IHSystem as authorized by Bio-Rad. The use of any material not specified in the U.S. User Manual (e.g. non-authorized substances) is forbidden.

6. Technological Characteristics

Substantial Equivalence Similarities

Parameter	Predicate Device IH-500 v2.1	Subject Device IH-500 v3.0
Classification	II	same
Product code	KSZ	same
510(k) number	BK180274	-
Regulation number	21 CFR 864.9175	same
Common name	IH-500 fully automated system for immunohematology diagnostics	same
Primary components	• Analyzer • One computer • Integrated adjustable touch screen monitor with keyboard • Software with license dongle • Hand-held bar code reader • Printer • Smartcard reader for user identification	same
Specimen types	Plasma, serum and red blood cells	same
Capability to process STAT samples	True Stat function, through the multimodule concept which ensures the highest range of flexibility in sample processing	same
QC procedures implemented	Yes	same
Barcode reading	Sample identification, reagent lot #, and expiration date	same
Manual entry of sample IDs or reagent data	Requires double blind entry with user identification	same

Parameter	Predicate Device IH-500 v2.1	Subject Device IH-500 v3.0
Sample loading - random access	Yes	same
Reagent positions	• 34 positions for RRBCs and solution racks min 2 adaptable to the appropriate sample number to be tested	same
Reagent Red Blood Cell suspension	• Cooled storing area for reagents with agitating movements for each reagent vial	same
Sample/reagent dispensing (pipetting) unit	• One pipetting arm, with access to the loaded reagents and samples	same
Card transport system	• 6-axis robot transport arm with gripper and presence sensor controlled; Internal camera contains the barcode reading function	same
Incubator	Two independent temperature areas: Pipetting area: room temperature Incubation area: 37°C	same
Centrifuge	2 independent centrifuges (2x12 IHCards) to ensure fast automated sample processing at all times	same
Total speed	• ABO + rev. grouping approximately 60 samples per hour Antibody screening with 3 cell screen - approximately 82 samples per hour	same
System solutions and waste containers	• Wash Solution A in concentrated form as system liquid • NaOH 0.5M as decontamination liquid • Microcide as decontamination solution for weekly maintenance • Waste solution in separate cans Waste bin for IH-Cards	same
Dispense verification	Through automatic distribution control function of the system	same

Parameter	Predicate Device IH-500 v2.1	Subject Device IH-500 v3.0
Result reading	The software analyses the reaction strength of the image in the corresponding IH-Card	same
Test interpretation	The system analyses the image and determines the reaction strength for each micro tube of the IH-Card. The final result interpretation is done by	same
	the IH-Com software, using predefined rules.	
Reports	Daily journal Results and protocols QC reports Patient work list	same
Interfaces	Bidirectional with Laboratory Information System	same
Useful life	5 years minimum	same

Substantial Equivalence Differences

Parameter	Predicate Device Bio-Rad IH-500 Analyzer	Subject Device Bio-Rad IH-500 Analyzer
Indications for Use Statement	• The IH-500 is designed for automated blood grouping determination using IH Cards, utilizing hemagglutination and gel filtration as the principle of operation. The instrument is intended for detection of ABO, RhD (including weak D and partial D testing), Rh Pheno and Kell blood grouping for patient and donor samples, as well as detection and identification of clinically relevant antibodies, AHG crossmatch, and direct antiglobulin testing using the IH-System reagents.	• The IH-500 is designed for automated blood grouping determination using IH Cards, utilizing hemagglutination and gel filtration as the principle of operation. The instrument is intended for detection of ABO, RhD (including weak D and partial D testing), Rh Pheno and Kell blood grouping for patient and donor samples, as well as detection and identification of clinically relevant antibodies, AHG crossmatch, direct antiglobulin testing using the IH-System reagents **and antibody titration testing.**

Parameter	Predicate Device Bio-Rad IH-500 Analyzer	Subject Device Bio-Rad IH-500 Analyzer
Tests performed	• ABO blood group and Rh (D) antigen typing • CcEeK Typing • Antibody screening • Antibody identification • AHG crossmatch • Direct antiglobulin test	• ABO blood group and Rh (D) antigen typing • CcEeK Typing • Antibody screening • Antibody identification • AHG crossmatch • Direct antiglobulin test • Antibody titration testing
Sample loading capacity	50 samples 168 IH-Cards 34 reagent vials Continuous loading	50 samples 164 IH-Cards 34 reagent vials Continuous loading
Card loading capacity	168 IH-Cards	164 IH-Cards
Barcode type	• Code 39, 93, 128 • Interleaved 2 of 5 • EAN-8 • CODABAR with control character suppressed • UCC-EAN 128 with control character suppressed • ISBT 128 with specific characters EAN-13 (equal to UPC-A 13)	• Code 39, 93, 128 • Interleaved 2 of 5 • EAN-8 • CODABAR with control character suppressed • UCC-EAN 128 with control character suppressed • ISBT 128 with specific characters • EAN-13 (equal to UPC-A 13) • 2D (GTIN-14)

7. Conclusion

In support of this premarket notification two in-house studies at Bio-Rad were performed based on the written feedback from the FDA (BQ1701551/1; dated November 27, 2019).

A performance study was done to evaluate the potential impact caused by the change to the new software IH-500 version 3.0 with improved image interpretation and to demonstrate safety and effectiveness and substantial equivalence of the investigational IH-500 version 3.0 with the currently cleared IH-500 version 2.1.14.

The second study was executed to evaluate the performance of the IH-500 in preparing serial dilutions of samples for the titration of antibodies with the applicable IH-Cards and selected RRBCs in comparison to the tube method and to evaluate the titer reproducibility (precision).

The outcome of the studies performed demonstrates that the IH-500 analyzer version 3.0 is safe and effective for tests with the IH-reagents. The results demonstrate that the testing with the corresponding IH-reagents generate equivalent test results comparable to FDA cleared IH-500 version 2.1.14. The serial dilution function on IH-500 for titration of IgG antibodies and of ABO antibodies is at least equal sensitive compared to the tube method. All results from the precision testing indicated low variation in antibody titer results.