SECTION 6 – 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:

Bio-Rad Medical Diagnostics GmbH
Industriestrasse 1
63303 Dreieich, Germany

Contact: Dr. Marc Gorzellik
Phone: +49 (0) 6103 3130-528
Fax: +49 (0) 6103 3130-646

Date Summary Prepared: July 05, 2023

2. Device Name:

Device Trade Name:	IH-500
Version:	3.1
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
Version:	3.0
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated System for Blood Grouping and Antibody Test System
510(k) Number	BK210625
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Regulatory Class:	Class II
Clearance Letter	February 24, 2022

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 IH-System 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. Comparison to Predicate Device

Parameter	Predicate Device IH-500 v3.0	Subject Device IH-500 v3.1
Indications for Use Statement	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 IH-System 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.	same
Classification	II	same

Parameter	Predicate Device IH-500 v3.0	Subject Device IH-500 v3.1
Product code	KSZ	same
510(k) number	BK210625	-
Regulation number	21 CFR 864.9175	same
Common name	IH-500 fully automated system for immunohematology diagnostics	same
Software version	v3.0	v3.1
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 multi-module 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
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	• 6-axis robot transport arm with	same

Parameter	Predicate Device IH-500 v3.0	Subject Device IH-500 v3.1
system	gripper and presence sensor controlled; Internal camera contains the barcode reading function	
Incubator	Two independent temperature areas: Pipetting area: room temperature Incubation area: 37°C	same
Centrifuge	2 independent centrifuges (2x12 IH-Cards) to ensure fast automated sample processing at all times	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
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 the IH-Com software, using predefined rules.	same
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
Tests performed	• ABO blood group and Rh (D) antigen typing • CcEeK Typing • Antibody screening • Antibody identification • AHG crossmatch	

Parameter	Predicate Device IH-500 v3.0	Subject Device IH-500 v3.1
	• Direct antiglobulin test • Antibody titration testing	
Sample loading capacity	50 samples 164 IH-Cards 34 reagent vials Continuous loading	same
Card loading capacity	164 IH-Cards	same
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) • 2D (GTIN-14)	same

7. Conclusion

The verification and validation activities for IH-500 v3.1 have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements. Bio-Rad concludes, based on all information described in this submission that IH-500 v3.1 is safe, effective and substantially equivalent to the predicate device IH-500 v3.0.