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. Andreas Grosse
Phone: +49 (0) 6103 3130-580
Fax: +49 (0) 6103 3130-646

Date Summary Prepared: March 19, 2019

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

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

Device Trade Name:	IH-1000
Common Name:	IH-1000 Automated System for Blood Grouping and Antibody Test System
Classification Name:	Automated System for Blood Grouping and Antibody Test System
510(k) Number	BK170019
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Regulatory Class:	Class II
Clearance Letter	May 5, 2017

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

The IH-500 analyzer system consists of the following primary components:
- IH-500 analyzer
- Integrated adjustable 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, 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 and direct antiglobulin 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. **IH**-500 is only allowed to use gel cards and reagents from the IH-System authorized by Bio-Rad. The use of any material not specified in the User Manual US (e.g. non-authorized substances) is forbidden.

6. Technological Characteristics

Substantial Equivalence Similarities

Parameter	Predicate Device Bio-Rad IH-1000 Analyzer	Subject Device Bio-Rad IH-500 Analyzer
Indications for Use Statement	The IH-1000 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, and direct antiglobulin testing using the IH-System reagents.
Classification	II	II
Product code	KSZ	KSZ
510(k) number	BK170019	-
Regulation number	21 CFR 864.9175	21 CFR 864.9175
Common name	IH-1000 fully automated system for immunohematology diagnostics	IH-500 fully automated system for immunohematology diagnostics
Tests performed	• ABO blood group and Rh (D) antigen typing • CcEeK Typing • Antibody screening	• ABO blood group and Rh (D) antigen typing • CcEeK Typing • Antibody screening

Parameter	Predicate Device Bio-Rad IH-1000 Analyzer	Subject Device Bio-Rad IH-500 Analyzer
	• Antibody identification • AHG crossmatch • Direct antiglobulin test	• Antibody identification • AHG crossmatch • Direct antiglobulin test
Specimen types	Plasma, serum and red blood cells	Plasma, serum and red blood cells
Capability to process STAT samples	True Stat function, through the multi-module concept which ensures the highest range of flexibility in sample processing	True Stat function, through the multi-module concept which ensures the highest range of flexibility in sample processing
QC procedures implemented	Yes	Yes
Barcode reading	Sample identification, reagent lot #, and expiration date	Sample identification, reagent lot #, and expiration date
Manual entry of sample IDs or reagent data	Requires double blind entry with user identification	Requires double blind entry with user identification
Sample loading - random access	Yes	Yes
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)
Incubator	Two independent temperature areas: Pipetting area: room temperature Incubation area: 37°C	Two independent temperature areas: Pipetting area: room temperature Incubation area: 37°C
Dispense verification	Through automatic distribution control function of the system	Through automatic distribution control function of the system
Result reading	The software analyses the reaction strength of the image in the corresponding IH-Card	The software analyses the reaction strength of the image in the corresponding IH-Card
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.	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.
Reports	Daily journal Results and protocols QC reports Patient work list	Daily journal Results and protocols QC reports Patient work list
Interfaces	Bidirectional with Laboratory Information System	Bidirectional with Laboratory Information System
Useful life	5 years minimum	5 years minimum
Operating system	Microsoft Windows Operating System Windows 7 Ultimate Service Pack 1 (32 bit)	Microsoft Windows Operating System Windows 7 Ultimate Service Pack 1 (32 bit)

Substantial Equivalence Differences

Parameter	Predicate Device Bio-Rad IH-1000 Analyzer	Subject Device Bio-Rad IH-500 Analyzer
Primary components	• Analyzer • Two computers • Integrated adjustable touch screen monitor with keyboard • Software with license dongle • Hand-held bar code reader • Printer • Smartcard reader for user identification	• 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
Reagent positions	28 position for RRBCs and solution racks min 2 adaptable to the appropriate sample number to be tested	34 positions for RRBCs and solution racks min 2 adaptable to the appropriate sample number to be tested
Reagent Red Blood Cell suspension	Motorized reagent rack with agitating movement	Cooled storing area for reagents with agitating movements for each reagent vial
Sample/reagent dispensing (pipetting) unit	Two independent pipetting arms with access to the loaded reagents and samples	One pipetting arm, with access to the loaded reagents and samples
Card transport system	Transport arm with gripper and presence sensor controlled, including barcode reading function	6-axis robot transport arm with gripper and presence sensor controlled; Internal camera contains the barcode reading function
Sample loading capacity	180 samples 240 IH-Cards 28 reagent vials Continuous loading	50 samples 168 IH-Cards 34 reagent vials Continuous loading
Card loading capacity	240 IH-Cards	168 IH-Cards
Centrifuge	3 independent centrifuges (3x12 IH-Cards) to ensure fast automated sample processing at all times	2 independent centrifuges (2x12 IH-Cards) to ensure fast automated sample processing at all times
Total speed	• ABO + rev. grouping approximately 80 samples per hour • Antibody screening with 3 cell screen - approximately 144 samples per hour	• ABO + rev. grouping approximately 60 samples per hour • Antibody screening with 3 cell screen - approximately 82 samples per hour
System solutions and waste containers	• Decon 90 as system liquid • Microcide as decontamination solution • Waste solution in separate cans • Waste bin for IH-Cards	• 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

7. Performance Characteristics:

a) Non-clinical Performance characteristics

Evaluation studies on electromagnetic compatibility and electrical safety were performed and confirmed that IH-500 is a safe and effective device.

Additionally Bio-Rad conducted performance bench testing to evaluate samples with interfering substances when tested with IH-System reagents for Blood Grouping including ABO serum grouping, weak D testing, and detection and identification of unexpected antibodies. Shelf life stability, on-board stability, and a study with well-characterized samples were also performed at Bio-Rad. The testing included the evaluation of the IH-Cards and associated reagents when tested on the IH-500 analyzer.

b) In-House and Clinical Performance Characteristics

Clinical studies were performed at three US clinical sites and one internal site using Bio-Rad's IH-500, including IH-System reagents and IH-Com software and FDA licensed reference methods. The purpose of these studies was to evaluate the performance of IH-500 for ABO+D Blood Grouping including weak D testing, antibody screening and identification, direct antiglobulin testing and antiglobulin crossmatch testing. Samples were collected from both blood donors and patients. The evaluation included more than 19,569 tests using samples from a diverse population in broad geographical areas.

The results of the clinical studies and the results of the in-house performance study confirm that IH-500 (in combination with IH-System reagents and IH-Com software) generates results equivalent to established FDA licensed reference reagents and FDA approved predicates for ABO+D Blood Grouping including weak D testing, antibody screening and identification, direct antiglobulin testing and antiglobulin crossmatch testing.

c) Reproducibility study

The Reproducibility Study was conducted at three external sites using one lot of Bio-Rad Blood Grouping Reagents, Reagent Red Blood Cells, and Anti-Human Globulin Reagents in IH-Cards. At each site, each product was tested using an identical panel of samples on the IH-500 analyzer. Testing occurred on five non-consecutive test dates over a 20 day period. On each day of testing, one operator tested in duplicate twice a day: one lot of reagents x 3 sites x 5 days x 2 runs (AM and PM) x 2 replicates. The results demonstrated reproducibility for the Blood Grouping Reagents, Anti-Human Globulin and Reagent Red Blood Cells in IH-Cards within runs, between runs, and within sites when tested on the IH-500 according to the instructions for use and the User Manual of the IH-500.

8. Conclusion

Bio-Rad concludes that testing of IH-Cards for Blood Grouping and Anti-Human Globulin Testing and corresponding Reagent Red Blood Cells on the IH-500 analyzer is safe and effective for automated blood grouping and antibody detection testing. The results demonstrate that end users, with proper training, could use the IH-500 to perform ABO+D cellular and serum grouping, RH+K phenoptyping, weak D testing, detection and identification of unexpected antibodies, DAT and AHG crossmatching, and that the testing with the specified IH-reagents generates test results comparable to an FDA licensed comparator method.