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.

Submitter´s Details

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Date of Summary:	December 16, 2020

Name of Device

Trade or Proprietary Name:	IH-1000
Common Name:	IH-1000 Automated System for Blood Grouping and Antibody Test
Classification Name:	Automated Blood Grouping and Antibody Test System
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

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

Description of the Device

IH-1000 instrument is an automated analyzer for processing samples and Bio-Rad´s IH-Reagents to execute tests and analyze the resulting reaction strength for blood grouping and antibody detection as listed below. It is used in conjunction with the IH-Com software, which is a test result interpretation and data management software designed for laboratories and blood banks. The automated process at the IH-1000 analyzer 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 also possible to compile and transmit information to an existing Laboratory Information System (LIS).

The IH-1000 Analyzer is handling 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)
- Crossmatching
- Auto control

The IH-1000 Analyzer system consists of the following primary components:

- IH-1000 Analyzer
- Integrated adjustable touch screen monitor with keyboard
- Hand-held barcode reader
- Printer
- Smartcard reader for user identification

Intended Use

The IH-1000 is an automated instrument intended for the in vitro serological analysis for blood grouping and antibody detection of human blood specimens. In the USA, IH-1000 is “Rx only”. The IH-1000 automates pipetting of samples and reagents, incubation and centrifugation, provides reaction grading / interpretation based on results from gel card images.

The IH-1000 may only be operated by trained personnel and is not intended for use in a direct patient environment. 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.

Use of the IH-1000 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. IH-1000 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 NA (e.g. non-authorized substances) is forbidden.

Comparison to Predicate Device

Parameter	**Predicate Device Bio-Rad IH-1000 Analyzer (v 04.04.52)**	**Updated Device Bio-Rad IH-1000 Analyzer (v 04.08)**
Similarities		
Indications for Use	The IH-1000 is an automated instrument intended for the in vitro serological analysis for blood grouping and antibody detection of human blood specimens. In the USA, IH-1000 is "Rx only". The IH-1000 automates pipetting of samples and reagents, incubation and centrifugation, provides reac-tion grading / interpretation based on results from gel card images.	same
Classification	II	same
Product Code	KSZ	same
Regulation Number	21 CFR 864.9175	same
510(k) Number	BK170019	-
Software Version	v 04.04.52	v 04.08
Tests performed	• Blood Grouping and Rh(D) Antigen typing • Weak D testing • Rh phenotyping (C, c, E, e) and Kell blood grouping (K) • Antibody Screening • Antibody Identification • AHG Crossmatch • Direct Antiglobulin Testing • Auto control	same
Primary components	• Analyzer • Two Computers • Integrated adjustable touch screen	same

Parameter	Predicate Device Bio-Rad IH-1000 Analyzer (v 04.04.52)	Updated Device Bio-Rad IH-1000 Analyzer (v 04.08)
	monitor with keyboard • IH-Com software • Hand-held barcode reader • Printer • Smartcard reader for user identification	
Specimen Types	Plasma, Serum and Red Blood Cells	same
Barcode Reading	Sample Identification Reagent Lot number Expiration Date	same
Manual Entry of Sample IDs or Reagent Data	Requires Double Blind Entry with User identification	same
Sample Loading Capacity	180 samples Continuous loading	same
Card loading capacity	240 IH-Cards	same
Card Transport system	Yes	same
Sample Barcode	1D Barcode	same
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)	same
Reagent positions	28 positions for Reagent Red Blood Cells and solution racks (minimum 2, adaptable to the appropriate sample number to be tested).	same
Reagent Red Blood Cell suspension	Motorized reagent rack with agitating movements.	same

Parameter	Predicate Device Bio-Rad IH-1000 Analyzer (v 04.04.52)	Updated Device Bio-Rad IH-1000 Analyzer (v 04.08)
Extra volume	The reagent extra volume aspirated by the probe is a fixed value.	same
Sample/ Reagent Dispensing Unit	Two independent pipetting arms with access to the loaded reagents and samples.	same
Dispense Verification	Yes	same
Incubator	Two independent temperature areas: Pipetting area: room temperature; Incubation area: 37°C	same
Centrifuge	3 independent centrifuges; 3 x 12 IH-Cards	same
Centrifugation	1008 rpm, 600 s	same
Motor driver	Integrated system module	same
Results reading	Camera interprets the result of the reaction in the corresponding IH-Card together with IH-Com.	same
Image acquisition board	No image acquisition board inside; IH-1000 uses USB cameras	same
Test interpretation	Computer algorithm analyzes the image and determines the reaction result for each micro tube of the IH-Card.	same
Operating system	Microsoft Windows Operating System Windows 7 Ultimate Service Pack 1 (32 bit).	Microsoft Windows Operating System Windows 10

CONCLUSION

The verification and validation activities for IH-1000 (v.04.08) have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements. Additional in-house performance studies were done to confirm safety and effectiveness of the device.

Bio-Rad concludes, based on all information described in this submission that IH-1000 v04.08 is safe, effective and substantially equivalent to the predicate device.