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:	April 06, 2017

Name of 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

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	ORTHO ProVue™ Analyzer Common
Name:	Automated Blood Bank Analyzer
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK110029
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	July 14, 2011

Device Description

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 Micro Typing Systems Inc. ORTHO ProVue™ Analyzer**	**Subject Device Diagnostic Bio-Rad IH-1000 Analyzer System**
Substantial Equivalence Similarities		
Indications for Use Statement	The ORTHO ProVue™ Analyzer is a modular, microprocessor-controlled instrument designed to automate in vitro immunohematological testing of human blood utilizing the ID-MTS Gel Card technology. As a standalone or interfaced to the customer`s Laboratory Information System (LIS), the ORTHO ProVue™ Analyzer automates test processing functions and data management requirements using gel cards and digital image processing.	The IH-1000 is designed for automated Blood Grouping Determination using IH-Cards, utilizing hemagglutination and gel filtration as principle of operation. The instrument is intended to perform the 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 clinical relevant antibodies, cross matching and Direct Antiglobulin testing using the IH-System reagents.
Tests Performed	• Blood Group and Rh (D) Antigen typing • Antibody Screening • Antibody Identification • IgG-Crossmatch • Direct Antiglobulin Testing • ABO Compatibility	• 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
Primary components	Analyzer Computer Software Hand-held bar code reader Printer	Analyzer Computer Integrated adjustable touch screen monitor with keyboard Software Hand-held bar code reader Printer

Parameter	**Predicate Device Micro Typing Systems Inc. ORTHO ProVue™ Analyzer**	**Subject Device Diagnostic Bio-Rad IH-1000 Analyzer System**
		Smartcard reader for user identification
Specimen Types	Plasma, Serum and Red Blood Cells	Plasma, Serum and Red Blood Cells
Diluents	MTS Diluent 2 Plus™ for the dilution of sample red cells for use with appropriate MTS Cards	IH-LISS Rack for the dilution of sample red cells for use with appropriate IH-Cards
Capability to process STAT samples	Yes	Yes 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 No. And Expiration Date	Sample Identification Reagent Lot No. And Expiration Date
Manual Entry of Sample Ids or Reagent Data	Requires Double Blind Entry	Requires Double Entry with User identification
Sample Loading Random Access	Yes	Yes
Sample Loading capacity	48 tubes simultaneously; 1 carousel	180 samples 240 IH-Cards 28 Reagent vials Continuous loading
Sample Barcode	Code 128	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)
Type	Codabar/NW7/Nisseki, Mod 11, Mod 16 Code 3 of 9 Code 2 of 5	Code 39, 93, 128 Interleaved 2 of 5 EAN-8 CODABAR with control character

Parameter	**Predicate Device Micro Typing Systems Inc. ORTHO ProVue™ Analyzer**	**Subject Device Diagnostic Bio-Rad IH-1000 Analyzer System**
	EAN-8 ISBT EAN-13/JAN	Suppressed UCC-EAN 128 with control character suppressed ISBT 128 with specific characters EAN-13 (equal to UPC-A 13)
Reagent positions	18 positions (16 for RRBCs and 2 for Diluents); 1 carousel	28 position for RRBCs and solution racks min 2 adaptable to the appropriate sample number to be tested
Reagent Red Blood Cell Suspension	Maintained by Rotation Movement	The reagents rack is motorized with agitating movement
Sample/Reagent Dispensing (pipetting) Unit (Substance collection and dispensing into the micro tubes)	Single probe to dispense samples and reagents	Two independent pipetting arms with access to the loaded reagents and samples
Card loading capacity	24 cards	240 IH-Cards
Card Transport system	Yes	Yes. Transport arm with gripper and presence sensor controlled including barcode reading function
Incubator	Two independent temperature areas that can be set up independently at 37°C or 24°C.	Two independent temperature areas: Pipetting area: room temperature Incubation area: 37°C
Centrifuge	1 Centrifuge; 12 cards capacity	3 independent centrifuges (3x12 IH-Cards) to ensure fast automated sample processing at all time
Dispense Verification	Yes. After card processing, by image analysis	Through automatic distribution control function of the system
Results reading	Yes. Microtube Digital Image Analysis	Yes. The software analyses the reaction strength of the image in the corresponding IH-Card
Test interpretation	Yes. according to predefined rules stated in a definition file (specific for MTS Gel System)	The analyzer analyses the image and determines the reaction strength for each micro tube of the IH-Card. The final result interpretation by predefined rules is done by the IH-Com software

Parameter	Predicate Device Micro Typing Systems Inc. ORTHO ProVue™ Analyzer	Subject Device Diagnostic Bio-Rad IH-1000 Analyzer System
Reports	Batch listing, Listing by Batch and Results by sample reports	Daily journal Results and protocols QC reports Patient work list
System solutions and waste containers	Wash Solution A Wash Solution B Waste solutions Process cards disposal	Decon 90 as system liquid Microcide as decontamination solution Waste solution in separate cans Waste bin for IH-Cards
Total speed	22 samples (ABO/Rh cards) per hour, including forward & reverse group	ABO + rev. grouping approximately 80 samples per hour Antibody screening with 3 test cells approximately 144 samples per hour
Interfaces	Bidirectional with Laboratory Information System	Bidirectional with Laboratory Information System
Useful life	5 years minimum considering a normal function of 160 cards/day and 250 days/year	5 years minimum
Operating system	• Windows XP Professional with Service Pack 3	• Microsoft Windows Operating System Windows 7 Ultimate Service Pack 1 (32 bit)

Performance Testing

a) Device Comparison Study

To evaluate the changes made to the IH-1000, an in-house comparison testing with FDA-approved IH-1000 (BK140106) was performed to show that neither safety nor effectiveness of IH-1000 was affected by the hardware and software changes.

Representative test assays for Blood Grouping including ABO reverse testing, Rh D including weak D, Rh and Kell phenotyping, antibody detection (and identification), DAT and crossmatching were tested. The study endpoint was an agreement for each single well result between IH-1000 versions as well as the IH-Com result compilation. The results obtained with updated IH-1000 (v.04.04.52) were compared with results obtained with FDA approved IH-1000. Testing with updated IH-1000 demonstrated no titer level difference compared to testing on the FDA-approved IH-1000 after visual verification. An equal antibody detection sensitivity was demonstrated by using both IH-1000 versions.

b) Clinical Performance Characteristics

The IH-1000 instrument is used in conjunction with the IH-Com software. The IH-Com software has a function to set parameters that define when results must be visually verified by an operator before they are released. The parameter can be adjusted to require operator verification of all results or of only selected results.

An analysis of the data from clinical studies and in-house studies support that visual verification is required for only a certain group of microtube results and for indeterminate and discrepant overall results and that all clear positive and clear negative results do not require visual verification by the user.

The results from the study reports demonstrate that end users can use the IH-1000 Analyzer in conjunction with the IH-Com and the settings described in the IH-Com User Manual for verification of results to perform ABO+D cellular and serum grouping, Phenotyping, weak D testing and detection and identification of unexpected antibodies, crossmatching and direct antiglobulin testing, and that the testing with the specified IH reagents on the IH-1000 Analyzer and the IH-Com software generates results comparable to established FDA licensed reference reagents and FDA approved predicates.

c) Conclusion

Bio-Rad concludes, based on all information submitted and discussed in this submission and this summary that IH-1000 is safe, effective and substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the U.S.A.