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:	September 16, 2016

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:	BK140106
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

The 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-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
- IH-Com software
- Two computers
- 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.

It generates results from individual images that must be verified by visual inspection and editing by a qualified person called a validator. 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.

Comparison to Predicate Device

IH-1000 and predicate device ORTHO ProVue® are compared based on intended use and technological characteristics. Both automated devices IH-1000 and ORTHO ProVue® are designed for performing immunohematology assays using gel card technology.

Parameter	**Predicate Device** **Micro Typing Systems** **ORTHO ProVue® Analyzer**	**Subject Device** **Bio-Rad** **IH-1000 Analyzer System**
Indication for Use	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 instrument 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 Blood Grouping Determination using the IH-Cards, utilizing hemagglutination and gel filtration as principles 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 clinically relevant antibodies, cross matching and Direct Antiglobulin testing using the IH-System reagents. The instrument generates results from individual images that must be verified by visual inspection and editing by a qualified operator.
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 barcode reader • Printer	• Analyzer • Two Computers • Integrated adjustable touch screen monitor with keyboard • IH-Com software • Hand-held barcode reader • Printer • Smartcard reader for user identification
Operating system	• Windows 2000 Professional with Service Pack 2 • Windows XP Professional with	• Windows XP Professional with Service Pack 3

Parameter	**Predicate Device** **Micro Typing Systems** **ORTHO ProVue® Analyzer**	**Subject Device** **Bio-Rad** **IH-1000 Analyzer System**
	Service Pack 3	
Specimen Types	Plasma, Serum and Red Blood Cells	Plasma, Serum and Red Blood Cells
Capability to process STAT samples	Yes	Yes
QC procedures implemented	Yes	Yes
Barcode Reading	Sample Identification Reagent Lot number Expiration Date	Sample Identification Reagent Lot number Expiration Date
Manual Entry of Sample IDs or Reagent Data	Requires Double Blind Entry	Requires Double Blind Entry with User identification
Sample Loading Random Access	Yes	Yes
Sample Loading Capacity	48 tubes simultaneously; 1 carousel	180 samples Continuous loading
Sample Barcode	1D Barcode	1D Barcode
Type	Code 128 Codabar/NW7/Nisseki, Mod 11, Mod 16 Code 3 of 9 Code 2 of 5 EAN-8 ISBT EAN-13/JAN	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)
Reagents	• ID-MTS™ Gel Cards • ORTHO Clinical Diagnostics Reagents	• IH-Cards • IH-System Reagents
Reagent positions	18 positions (16 for Reagent Red Blood Cells and 2 for diluents); 1 carousel	28 positions for Reagent Red Blood Cells and solution racks (minimum 2, adaptable to the appropriate sample number to be tested)
Reagent Red Blood Cell suspension	Maintained by rotation movement	Motorized reagent rack with agitating movements

Parameter	Predicate Device Micro Typing Systems ORTHO ProVue® Analyzer	Subject Device Bio-Rad IH-1000 Analyzer System
System solutions and waste containers	Wash Solution A Wash Solution B Waste solutions Process card disposal	Decon 90 as System liquid Microcide as decontamination solution Waste solution Waste bin for IH-Cards
Extra volume	The reagent extra volume aspirated by the probe is a fixed value.	The reagent extra volume aspirated by the probe is a fixed value.
Diluents	MTS Diluent 2 Plus™ for the dilution of Sample Red Blood Cells for use with appropriate ID-MTS™ Gel Cards.	IH-LISS Rack for the dilution of Sample Red Blood Cells for use with appropriate IH-Cards.
Sample/ Reagent Dispensing Unit	Single probe to dispense samples and reagents.	Two independent pipetting arms with access to the loaded reagents and samples.
Dispense Verification	Yes	Yes
Card loading capacity	24 cards	240 IH-Cards
Card Transport system	Yes	Yes
Material of the probe wash station	The material of the probe wash station is polysulfone.	Two stainless steel probes with FEP coating are used.
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
Incubator Temperature Tolerance	Incubator temperature specification at 37°C ± 2 °C	Incubator temperature specification at 35 – 38 °C
Centrifugation	1 centrifuge; 12 cards capacity	3 independent centrifuges; 3 x 12 IH-Cards
Centrifuge speed	1000 rpm to meet the requirements of the ID-MTS Gel Cards	1008 rpm to meet the requirements of the IH-Cards
Centrifugation time	600 s to meet the requirements of the ID-MTS™ Gel Cards	600 s to meet the requirements of the IH-Cards
Imbalance detection system	The instrument includes an imbalance detection system that detects when the centrifuge is imbalanced.	The instrument includes an imbalance detection system that detects when the centrifuge is imbalanced.
Motor driver	The motor driver is the HTCL1100	Integrated system module
Results reading	Microtube Digital Image Analysis	Camera interprets the result of the reaction in the corresponding IH-Card together with IH-Com
Image acquisition board	The image acquisition board is the Meteor II/Standard.	No image acquisition board inside; IH-1000 uses USB cameras

Parameter	Predicate Device Micro Typing Systems ORTHO ProVue® Analyzer	Subject Device Bio-Rad IH-1000 Analyzer System
Test interpretation	According to predefined rules stated in a definition file (specific for ID-MTS™ Gel Card System).	Computer algorithm analyzes the image and determines the reaction result for each micro tube of the IH-Card.
Test scripts	Test scripts are specific for the ORTHO ProVue® and are requested based on the market needs.	Test scripts are specific for the IH-1000 and are requested based on the market needs.
Reports	• Batch listing • Listing by Batch • Results by sample reports	• Daily journal • Results and protocols • QC reports • Patient work list
Total speed	22 samples (ABO/Rh cards) per hour, including forward & reverse group	ABO + Reverse grouping approximately 80 samples per hour; Antibody screening with 3 test cells approximately 144 samples per hour.
Interfaces	Bidirectional with Laboratory Information System (LIS)	Bidirectional with Laboratory Information System (LIS)
Useful Life	5 years minimum	5 years minimum

Description and Discussion of Testing

a) Non-clinical Performance characteristics

Evaluation studies on electromagnetic compatibility and electrical safety were performed and confirmed that IH-1000 is a safe and effective device.
Additionally Bio-Rad conducted performance bench testing with the investigational IH-System reagents for Blood Grouping including ABO serum grouping, weak D testing, detection and identification of unexpected antibodies. The purpose was to include in the evaluation samples with variations in collection and storage, samples with weak D antigen expression and samples with interfering substances. Shelf life stability, on board stability, sample aging, anticoagulant and limitations studies were also performed at Bio-Rad. The testing included the evaluation of the IH-Cards and associated reagents when tested on the IH-1000 Analyzer.

b) In-House and Clinical Performance Characteristics

Clinical studies were performed at four US sites using Bio-Rad's IH-1000, 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-1000 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 samples included more than 6,400 samples from a diverse population in broad geographical areas. Additional performance testing was conducted in-

house at Bio-Rad. Internally at Bio-Rad, additional antibody detection and identification tests were performed.

The results of the clinical studies and the results of the in-house performance study confirm IH-1000 (in combination with IH-System reagents and IH-Com software) to generate 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 and Lot-to-Lot study

The Reproducibility Study was conducted at three sites (two external and one internal) 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-1000 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, within sites and when tested on the IH-1000 according to the instructions for use and the User Manual of the IH-1000.

The Lot-to-Lot Study was conducted in-house at Bio-Rad using three (3) lots of Bio-Rad Blood Grouping Reagents, Reagent Red Blood Cells, and Anti-Human Globulin Reagents in IH-Cards. Each product was tested using a special panel of samples on the IH-1000 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: 3 lots x 1 site x 5 days x 2 runs (AM and PM) and 2 replicates.
The results demonstrated lot-to-lot agreement for the Blood Grouping Reagents, Anti-Human Globulin and Reagent Red Blood Cells when tested on the IH-1000 according to the instructions for use and the User Manual of the IH-1000.

Conclusion

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