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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Device Information

Device Name:	IH-Com V2.0-06/2016
Common Name:	IH-Com Data Management and Results Interpretation Software
Classification Name:	Software, Blood Bank, Stand Alone Products
510(k) number:	BK140107
Device Class:	II
Product Code:	MMH
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	ORTHO ProVue® 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-Com is a data management and result interpretation software application designed for immunohematological diagnostics. IH-Com software uses the image results from an Automated Blood Grouping and Antibody Test system, like the IH-1000 Analyzer, to determine the blood group and the antibody status of patient or donor samples analyzed by the instrument.

IH-Com is designed to provide an interface between the user, Bio-Rad instruments and the Laboratory Information System (LIS). Multiple systems can be connected in different physical locations through one single connection to the LIS. IH-Com allows the management and transfer of patient, donor, QC and sample data. Blood grouping and antibody test results obtained from connected instruments can be validated through one central user interface.

The main functions of IH-Com are:

- Interpretation of results
- Validation of results (user interface)
- Data management (patient, donor, results, users, etc.)
- Documentation (tracing of events, lot numbers, etc.)
- Bi-directional communication with connected instruments and the LIS
- Back-up and archiving of data
- Quality Control management

There are no specific environmental requirements for IH-Com. Hardware requirements are as follows:

- PC with INTEL or AMD CPU
- Dual-Core or Quad-Core
- Frequency $\geq$ 2GHz
- Memory $\geq$ 2GB
- Hard disk $\geq$ 100GB (rpm $\geq$ 7200)

Intended Use

IH-Com is software used exclusively with an in vitro diagnostic device. IH-Com is an interface used to control fully automated instruments, and to manage the data for patients, donors and samples. IH-Com may only be operated by trained personnel and is not intended for use in a direct patient environment.

Comparison to Predicate Device

The following table identifies the predicate device that was used to show equivalence of IH-Com with an already FDA approved device, covering the intended use of using image results from Automated Blood Grouping and Antibody Test systems to create the final test result.

Parameter	**Predicate Device** **Micro Typing Systems Inc.** **ORTHO ProVue® Analyzer**	**Subject Device** **Bio-Rad** **IH-Com V2.0-06/2016**
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.	IH-Com is a software package intended to be used as an interface between automated blood banking instruments and the Blood Establishment Computer Software. IH-Com is for use by trained laboratory personnel, in a blood banking environment, to assist with result interpretation, data management and instrument control.
Tests performed	● Blood Group and Rh(D) Antigen typing ● Antibody Screening ● Antibody Identification ● IgG-Crossmatch ● Direct Antiglobulin Testing ● ABO Compatibility	● Blood Group 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 Test ● Auto Control
Primary components	● Analyzer ● Computer ● Software ● Hand-held bar code reader ● Printer	● Computers ● Software with license dongle
Software	Incorporated into the computer of the analyzer.	Standalone software on a separate computer interfaced with one or more instruments.
Sample and patient data entry	Transmission via LIS interface, direct barcode reading or manual entry	Transmission via LIS interface, direct barcode reading or manual entry
Manual Entry of Sample IDs or Reagent Data	Requires Double Blind Entry	Requires Double Blind Entry with User identification
Overall test	According to predefined rules	Computer algorithm analyzes the

interpretation	stated in a definition file (specific for ID-MTS™ Gel Card System).	image and determines the reaction result for each micro tube of the IH-Card.
Reports	• Batch listing • Listing by Batch • Results by sample reports	• Daily journal • Sample result protocols • Patient result protocols • QC reports • Sample work list
Interfaces	Bidirectional with Laboratory Information System (LIS).	Bidirectional with the IH-1000 Analyzer and the Laboratory Information System (LIS).

Non-clinical performance characteristics

A risk analysis of the interface data management to the instruments was done. The in-house validation confirmed safety and effectiveness of software operation by evaluating all functions for installation and operation linked to an IH-1000 Analyzer.

Clinical Performance Characteristics and Conclusion

Clinical studies were performed at four US sites using Bio-Rad's IH-Reagents and FDA licensed comparator methods for the performance evaluation of the IH-1000 System for Blood Grouping including weak D testing, antibody screening and identification, direct antiglobulin testing and antiglobulin crossmatch testing. The study at the four sites included more than 6,400 samples from a diverse population in broad geographical areas. Within this performance evaluation, data were collected to evaluate performance aspects of IH-Com software connected to the IH-1000 Analyzer. During the multicenter study all requests were sent to the instrument and the corresponding image results received back for further assignment and evaluation. All data were correctly managed and displayed by IH-Com. There was no issue observed regarding safety and effectiveness of the software.

Bio-Rad concludes, based on all information submitted and discussed in this submission and this summary that IH-Com 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.