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

Trade / Device Name:	IH-Com V5.0
Common Name:	IH-Com Data Management and Results Interpretation Software
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK170021
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade / Device Name:	IH-Com V4.0
Common Name:	IH-Com Data Management and Results Interpretation Software
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK140107
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	October 20, 2016

Description of the Device

IH-Com V5.0 is a data management and result interpretation software designed only for immunohematological diagnostic purposes. IH-Com V5.0 software can be used only in combination with a Bio-Rad in vitro diagnostic device and is regarded as a "Rx only" product. The IH-Com V5.0 software is designed to provide an interface between the user, Bio-Rad instruments and the Laboratory Information System (LIS). It transfers orders for patient or donor samples to a blood banking test system like the IH-1000 and uses the image results for final test interpretation. The image results can be visually checked and verified in IH-Com V5.0 before result validation and report printing or result transfer to LIS. IH-Com V5.0 allows also the storage and management of patient, donor, QC, sample and reagent data.

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 ≥ 2GHz
- Memory ≥ 2GB
- Hard disk ≥ 100GB (rpm ≥ 7200)

Intended Use

IH-Com V5.0 is data management and result interpretation software used in immunohematology testing to analyze reaction images for blood samples that are tested on the IH-1000 with IH-System reagents. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with a standalone IH-1000, with multiple IH-1000s, or connected to a Laboratory Information System.

IH-Com V5.0 should only be operated by trained personnel and is not intended for use in a direct patient environment. In the USA IH-Com V5.0 is "Rx only".

Comparison to Predicate Device

The predicate device for this Traditional 510(k) submission is IH-Com V4.0, reviewed by the FDA under premarket notification BK140107 and determined substantially equivalent on October 20, 2016.

This Traditional 510(k) is submitted to modify a legally marketed device (predicate). The feature comparisons between the two versions of IH-Com are presented in table 1 below.

Table 1 Substantial Equivalence Comparison

Parameter	**Predicate Device** **Bio-Rad IH-Com V4.0 Software**	**Subject Device** **Bio-Rad IH-Com V5.0 Software**
Indications for Use Statement	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.	IH-Com V5.0 is data management and result interpretation software used in immunohematology testing to analyze reaction images for blood samples that are tested on the IH-1000 with IH-System reagents. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with a standalone IH-1000, with multiple IH-1000s, or connected to a Laboratory Information System. IH-Com V5.0 should only be operated by trained personnel and is not intended for use in a direct patient environment. In the USA IH-Com V5.0 is “Rx only”.
Classification	II	same
Product Code	KSZ	same
Regulation Number	21 CFR 864.9175	same
510(k) Number	BK140107	BK170021
Common Name	IH-Com V4.0	IH-Com V5.0

Parameter	**Predicate Device** **Bio-Rad IH-Com V4.0 Software**	**Subject Device** **Bio-Rad IH-Com V5.0 Software**
Tests managed	ABO and Rh typing Rh phenotyping Antibody Screening Antibody Identification AHG Crossmatch Direct Antiglobulin Test Auto Control	same
Primary components	• Computers • Software with license dongle	same
QC procedures implemented	Yes	same
Overall test interpretation	Computer algorithm analyzes combines the image result and generated final test results	same
Reports	• Daily journal • Sample result protocols • Patient result protocols • QC reports • Sample work list	same
Interfaces	Bidirectional with Laboratory Information System (LIS).	same
Operating System	Windows XP Professional SP3	Windows 7 Ultimate SP 1
Programming Language	Microsoft VB.NET (Visual Basic "Dotnet")	same

Performance Testing

a) Device Comparison Study

To evaluate the changes to the IH-Com software versions, IH-Com V5.0 was compared with FDA-approved IH-Com V4.0 as reference in an internal study. The objective of this in-house comparison testing was to show that neither safety nor effectiveness of the IH-Com used with IH-1000 was affected by the planned 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 performed. The results obtained with IH-Com V5.0 were compared with results obtained with FDA approved IH-Com V4.0. The study endpoint was an agreement in IH-Com result compilations.

Result compilations for each sample by IH-Com were in agreement between IH-Com V5.0 and IH-Com V4.0. Based on the obtained results IH-Com V5.0 has demonstrated equivalence with IH-Com V4.0, and therefore the use of IH-Com V5.0 is safe and effective for routine testing.

b) Clinical Performance Characteristics

IH-Com software is used in conjunction with the IH-1000 Analyzer. 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-Com V5.0 is safe, effective and substantially equivalent to the predicate device (IH-Com V4.0) and has been demonstrated to meet all requirements for a product to be marketed in the U.S.A.