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:	Data Management and Results Interpretation Software
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 / Device Name:	IH-Com V5.0
Common Name:	Data Management and Results Interpretation Software
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK180226
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	September 28, 2018

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 can be used only in combination with a Bio-Rad in vitro diagnostic device and is regarded as "Rx only".
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-500, IH-Reader 24, IH-1000 or TANGO infinity 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 V5.0 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 V5.0. 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, IH-500 and IH-Reader 24 with IH-System reagents or the TANGO infinity® with reagents specifically formulated and manufactured by Bio-Rad Medical Diagnostics GmbH. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with:

• a standalone or multiple IH-1000 systems,
• a standalone or multiple IH-500 systems,
• a standalone or multiple IH-Reader 24 systems,
• a standalone TANGO infinity® or multiple TANGO infinity® systems;

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 is "Rx only".

Comparison to Predicate Device

The predicate device for this Special 510(k) submission is IH-Com V5.0, reviewed by the FDA under BK180226. The substantial equivalence comparison of the subject and predicate device is presented in Table 1 below.

Table 1 Device Comparison Table

Parameter	**Predicate Device** **Bio-Rad IH-Com V5.0 Software**	**Subject Device** **Bio-Rad IH-Com V5.0 Software**
Intended Use Statement	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 and IH-Reader 24 with IH-System reagents or the TANGO infinity® with reagents specifically formulated and manufactured by Bio-Rad Medical Diagnostics GmbH. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with: • a standalone or multiple IH-1000 systems, • a standalone or multiple IH-Reader 24 systems, • a standalone TANGO infinity® or multiple TANGO infinity® systems; or connected to a Laboratory Information System. IH-Com V5.0 should only be operated by trained personnel and is	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, IH-500 and IH-Reader 24 with IH-System reagents or the TANGO infinity® with reagents specifically formulated and manufactured by Bio-Rad Medical Diagnostics GmbH. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with: • a standalone or multiple IH-1000 systems, • a standalone or multiple IH-500 systems, • a standalone or multiple IH-Reader 24 systems, • a standalone TANGO infinity® or multiple TANGO infinity® systems; or connected to a Laboratory

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.0 Software
	not intended for use in a direct patient environment. In the USA IH-Com is “Rx only”.	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 is “Rx only”.
Classification	II	same
Product Code	KSZ	same
Regulation Number	21 CFR 864.9175	same
510(k) Number	BK180226	-
Common Name	IH-Com V5.0	same
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	Software algorithm analyzes and combines image results and generates 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) • Additional IH-Web interface for user access from outside locations	same
Operating System	Windows 7 Ultimate SP 1	same

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.0 Software
Programming Language	Microsoft VB.NET (Visual Basic "Dotnet")	same

Conclusion

This Special 510(k) is submitted to allow for a connection of IH-Com V5.0 to IH-500 Analyzer. The fundamental scientific technology of the proposed device is unchanged from the predicate (BK180226). Bio-Rad concludes, based on all information submitted and described in this submission and this summary, that IH-Com V5.0 is safe, effective and substantially equivalent to the predicate device.