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

Name:	Bio-Rad Medical Diagnostics GmbH
Address:	Industriestrasse 1, 63303 Dreieich, Germany
Establishment Registration Number:	9610824
Contact:	Dr. Marc Gorzellik
Telephone number:	+49 (0) 6103 3130-528
Fax number:	+49 (0) 6103 3130-646
Date of Summary:	November 29, 2019

Name of Device

Trade or Proprietary Name:	IH-Com V5.2
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:	BK180275
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	March 21, 2019

DESCRIPTION OF THE DEVICE

IH-Com is a software package intended to be used as an interface between automated blood banking instruments and the Laboratory Information System (LIS). 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 is a data management and result interpretation software designed only for immunohematological diagnostic purposes.

IH-Com 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 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 before result validation and report printing or result transfer to LIS.

IH-Com 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 V5.2 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 V5.2 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 V5.2 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".

Recommendation: Operators of IH-Com V5.2 have to be trained by authorized personnel and have to be familiar with the content of this IH-Com V5.2 User Manual U.S. The IH-Com V5.2 User Manual U.S. is designed to serve as a reference manual for operations and safety instructions.

Comparison to Predicate Device

The predicate device for this Special 510(k) submission is IH-Com V5.0, reviewed by the FDA under BK180275. The substantial equivalence comparison of the subject and predicate device is presented in Table 1 below.

Table 1: Substantial Equivalence Comparison

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.2 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, 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,	IH-Com V5.2 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.

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.2 Software
	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”.	IH-Com V5.2 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 V5.2 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”. Recommendation: Operators of IH-Com V5.2 have to be trained by authorized personnel and have to be familiar with the content of this IH-Com V5.2 User Manual U.S. The IH-Com V5.2 User Manual U.S. is designed to serve as a reference manual for operations and safety instructions.
Classification	II	same
Product Code	KSZ	same
Regulation Number	21 CFR 864.9175	same
510(k) Number	BK180275	-
Common Name	IH-Com V5.0	IH-Com V5.2
Tests managed	ABO and Rh typing Rh phenotyping	same

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.2 Software
	Antibody Screening Antibody Identification AHG Crossmatch Direct Antiglobulin Test Auto Control	
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	Windows 7 Ultimate SP 1 Windows 10
Programming Language	Microsoft VB.NET (Visual Basic "Dotnet")	same

CONCLUSION

This Special 510(k) is submitted to release IH-Com V5.2 to the U.S. market. The fundamental scientific technology of the proposed device is unchanged from the predicate (BK180275). Bio-Rad concludes, based on all information submitted and described in this submission and this summary, that IH-Com V5.2 is safe, effective and substantially equivalent to the predicate device.