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 Person:	Dr. Rolf Vornhagen
Telephone number:	+49 (0) 6103 3130-442
Fax number:	+49 (0) 6103 3130-646
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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
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:	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
Clearance Letter:	May 05, 2017

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 $\geq$ 2GHz
- Memory $\geq$ 2GB
- Hard disk $\geq$ 100GB (rpm $\geq$ 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. The user can access selected functions of IH-Com V5.0 from remote locations using IH-Web V2.0. 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 V5.0, reviewed by the FDA under premarket notification BK170021 and determined substantially equivalent on May 05, 2017.

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 V5.0.9 Software**	**Subject Device** **Bio-Rad IH-Com V5.0.10 Software**
Indications for 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 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".	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. The user can access selected functions of IH-Com V5.0 from remote locations using IH-Web V2.0. 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	BK170021	BK170071
Common Name	IH-Com V5.0	same

Parameter	Predicate Device Bio-Rad IH-Com V5.0.9 Software	Subject Device Bio-Rad IH-Com V5.0.10 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	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)	same • additional IH-Web interface for user access from outside locations
Operating System	Windows 7 Ultimate SP 1	same
Programming Language	Microsoft VB.NET (Visual Basic "Dotnet")	same

Conclusion

The verification and validation activities for IH-Com V5.0.10 have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements.

This Traditional 510(k) is submitted to modify a legally marketed device (predicate). Bio-Rad Medical Diagnostics GmbH is the holder of the 510(k) for the predicate device. The Indications for Use of the proposed device are unchanged from the legally marketed device (predicate). The intended use of the modified device, as described in the labeling, has not changed as a result of the modifications. Finally, fundamental scientific technology of the proposed device is unchanged from the predicate (BK170021).

Bio-Rad concludes, based on all information submitted and described in this submission and this summary that IH-Com V5.0.10 is safe, effective and substantially equivalent to the predicate device.