Bio-Rad Medical Diagnostics GmbH
Attention: Dr. Rolf Vornhagen
Industriestrasse 1
D-63303 Dreieich
Germany

510(k) Number	BK140106	BK140107	BK140138	BK140139
Trade/Device Name	IH-1000	IH-COM	IH-Card Neutral	IH-Card Control
Regulation Number	21 CFR 864.9175	21 CFR 864.9175	21 CFR 864.9175	21 CFR 864.9650
Regulation Name	Automated Blood Grouping and Antibody Test Systems	Automated Blood Grouping and Antibody Test Systems	Automated Blood Grouping and Antibody Test Systems	Quality Control Kits for Blood Grouping Reagents
Regulatory Class	Class II	Class II	Class II	Class II
Product Code	KSZ	KSZ	KSZ	KSF
Dated	September 27, 2016	September 28, 2016	September 28, 2016	September 28, 2016
Received	September 27, 2016	September 28, 2016	September 28, 2016	September 28, 2016

Dear Dr. Vornhagen:

We have reviewed your Section 510(k) premarket notifications of intent to market the devices referenced above and have determined theses device are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898.

In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Orieji Illoh, MD
Acting Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications For Use

Indications for Use

510(k) Number: BK140106

Device Name: IH-1000

Indications For Use:

The IH-1000 is designed for Blood Grouping Determination using the IH-Cards, utilizing hemagglutination and gel filtration as principles of operation.

The instrument is intended to perform the detection of ABO, RhD (including weak D and partial D testing), Rh Pheno and Kell blood grouping for patient and donor samples as well as detection and identification of clinically relevant antibodies, cross matching and Direct Antiglobulin testing using the IH System reagents. The instrument generates results from individual images that must be verified by visual inspection and edited by a qualified operator.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Device Evaluation (ODE)

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Division Sign-Off, Office of Blood Research and Review

Indications for Use

510(k) Number: BK140107

Device Name: IH-COM

Indications For Use:

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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review

Indications for Use

510(k) Number: BK140138

Device Name: IH-Card Neutral

Indications For Use:

For serum grouping to be used with IH-Cell A2 on the IH-1000 Analyzer.

Prescription Use_X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review

Indications for Use

510(k) Number: BK140139

Device Name: IH-Card Control

Indications For Use:

IH-Card Control is intended for use as a supplemental control for IH-Cards with monoclonal Blood Grouping Reagents on the IH-1000 Analyzer.

Prescription Use_X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Blood Research and Review

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