

February 28, 2022

Bio-Rad Medical Diagnostics GmbH Attention: Mr. David Bhend Bio-Rad Laboratories Inc. 6565 185th Ave NE Redmond, WA 98052

Re: BK210625

Trade/Device Name: IH-500

Regulation Number: 21 CFR 864.9175

Regulation Name: Automated blood grouping and antibody test system

Regulatory Class: Class II Product Code: KSZ

Dated: February 24, 2022 Received: February 24, 2022

Dear Mr. Bhend:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is 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 the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.identifies.combination

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-device-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD 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: BK210625
Device Name: IH-500
Indications for Use:
The IH-500 is an automated instrument intended for the in vitro serological analysis for blood grouping and antibody detection of human blood specimens. The IH-500 automates pipetting of samples and reagents, incubation and centrifugation, and provides reaction grading / interpretation based on results from gel card images. Analysis includes ABO, Rh(D) (including weak D and partial D testing), Rh Phenotype and Kell blood grouping, antibody screening and identification of red blood cell alloantibodies, crossmatch, auto control, direct antiglobulin testing and antibody titration testing.
In the USA, IH-500 is "Rx only". The IH-500 may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-500 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad.
Use of IH-500 is only permitted with gel cards and reagents from the IH-System as authorized by Bio-Rad. The use of any material not specified in the U.S. User Manual (e.g. non-authorized substances) is forbidden.
Prescription Use X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review
Division Sign-Off Office of Blood Research and Review