



September 28, 2018

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

Re: BK180225

Trade/Device Name: IH-Reader 24
Regulation Number: 21 CFR 864.9175
Regulation Name: Automated blood grouping and antibody test systems
Regulatory Class: Class II
Product Code: KSZ
Dated: September 6, 2018
Received: September 7, 2018

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. 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 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for more information.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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: BK180225

Device Name: IH-Reader 24

Indications for Use:

The IH-Reader 24 is an instrument intended for the in vitro serological analysis of human blood specimens for blood grouping and antibody detection. IH-Reader 24 performs centrifugation and provides reaction grading / interpretation based on results from IH-System gel card images. In the USA, IH-Reader 24 is "Rx only".

The IH-Reader 24 may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-Reader 24 is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. IH-Reader 24 is allowed to use gel cards from the IH-System authorized by Bio-Rad. The use of any material not specified in the User Manual (e.g. non-authorized substances) is under the users' responsibility

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW 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