DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2016

Bio-Rad Laboratories
Maria Zeballos
Regulatory Affairs Representative
9500 Jeronimo Road
Irvine, CA 92614

Re: k152679
Trade/Device Name: Amplichek I
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: April 11, 2016
Received: April 11, 2016

Dear Ms. Zeballos:

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 (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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 device 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 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.

Sincerely yours,

Stephen J. Lovell -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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and Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k152679

Device Name
Amplichek I

Indications for Use *(Describe)*
Amplichek I is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the quantitative detection of Human Immunodeficiency Virus Type 1 (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) for molecular diagnostic platforms listed in the package insert. This product is not intended to replace manufacturer controls provided with the device.
This product is not intended for use with blood donor screening assays in U.S. or Canada.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1.0 Submitter

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Contact Person

Maria Zeballos
Regulatory Affairs Representative IV
Telephone: (949) 598-1367

Date of Summary Preparation

April 4, 2016

2.0 Device Identification

Product Trade Name:	Amplichek I
Common Name:	Assayed quality control material for clinical microbiology assays
Classifications:	Class II
Product Code:	PMN
Regulation Number:	21 CFR 866.3920

3.0 Device to Which Substantial Equivalence is Claimed

Amplichek II
Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
DEN150058

4.0 Description of Device

Amplichek I is a set of quality controls consisting of four levels filled in individual vials with 1.2 mL of material. Each level is packaged separately in configuration of 10 tubes per box and four tubes per box in a MiniPak (trial size).

This product is prepared from normal human plasma based material non-reactive to HIV-1 Ribonucleic Acid (RNA), HBV Deoxyribonucleic Acid (DNA) and HCV Ribonucleic Acid (RNA) with added proteins from human sources, antimicrobial agents as preservatives, and stabilizers.

The positive levels are prepared using purified preparations of HIV, HBV and HCV isolated from human plasma or grown in cell cultures and are reactive for HIV-1 RNA, HBV DNA and HCV RNA.

Amplichek I contains human plasma and purified retroviral and viral hepatitis materials derived from human plasma and/or cultured human cell line sources. Each human unit used in the preparation of this product is tested using licensed reagents and must be found to be non-reactive to HBsAg, antibodies to HIV-1 and HIV-2 and antibodies to HCV. Retroviral and viral hepatitis materials derived from human plasma and/or cultured human cell line sources are treated to inactivate infectious agents. However, no known test method can assure that products derived from human sources will not transmit infection. The labeling recommends that this product and all human specimens be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.

The package insert will provide lot specific mean and ranges for each analyte on various platforms. The assigned values listed in the proposed package insert were generated in the same manner as used for unknown specimens using FDA approved commercial test kits. The negative control reports qualitative results. The means for the positive controls were calculated from the total laboratory data generated for each analyte on the specific platform and the 3SD range was then assigned. The Amplichek I labeling recommends that each laboratory establish its own acceptable range for each analyte. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

Amplichek I product should not be used as a standard. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

5.0 **Intended Use**

Amplichek I is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the detection of Human Immunodeficiency Virus Type 1 (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) for molecular diagnostic platforms listed in the package insert. This product is not intended to replace manufacturer controls provided with the

device. This product is not intended for use in blood donor screening assays in the US or Canada.

6.0 Comparison of the new device with the Predicate Device

Bio-Rad Laboratories Amplichek I claim substantial equivalence Bio-Rad's Amplichek II (DEN 150058) currently in commercial distribution. The Table below contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table: Similarities and Differences between new and predicate devices

Characteristics	Bio-Rad Amplichek I (New Device)	Bio-Rad Amplichek II DEN 150058
Similarities		
Intended Use	Amplichek I is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the detection of Human Immunodeficiency Virus Type 1 (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) for molecular diagnostic platforms listed in the package insert. This product is not intended to replace manufacturer controls provided with the device. This product is not intended for use in blood donor screening assays in the US or Canada.	Amplichek II is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of Methicillin Resistant Staphylococcus aureus, Methicillin Sensitive Staphylococcus aureus, Clostridium difficile and Vancomycin-resistant Enterococci performed on Cepheid GeneXpert Systems. This product is not intended to replace manufacturer controls provided with the device. This product is only for use with assays and instruments listed in the Representative Results Chart in this labeling.
Form	Liquid	Liquid
Levels	4 Levels (Negative and Positive L1, L2 and L3)	4 Levels (Negative and Positive L1, L2 and L3)
Preservatives	Contains preservatives 0.09% Sodium azide	Contains preservatives 0.1% ProClin® 300 preservative
Stabilizers	Contains stabilizers	Contains stabilizers
Differences		
Open Vial Claim	7 days at 2 to 8°C or 3 vial entries whichever comes first	None
Matrix	Human plasma based	Aqueous buffered solution
Expected Results	For use with quantitative assays Lot specific results provided	For use with qualitative assays Representative results provided
Storage(Unopened)	Frozen (–20°C -70 °C) Until expiration date	2 to 8°C until expiration date
Analytes	HIV-1 HBV HCV	MRSA (Methicillin Resistant Staphylococcus aureus) MSSA (Methicillin Sensitive Staphylococcus aureus) Cdiff (Clostridium difficile) VRE (Vancomycin-resistant Enterococci)

7.0 Statement of Supporting Data

Stability studies have been performed to determine the shelf life at -20 to -70 °C, and open vial at claims at 2 to 8°C. Product claims are as follows:

7.1 Shelf Life at 20 to -70^{o}C, all analytes will be stable for 16 months.

7.2 The open vial stability claim for Amplichek I is 7 days or 3 vial entries whichever comes first, when stored tightly capped at 2 to 8°C

All supporting data is retained on file at Bio-Rad Laboratories.

8.0 **Conclusion**

Based on the performance characteristics indicated above, the Bio-Rad Amplichek I is substantially equivalent to the predicate device: Amplichek II DEN 150058