BioPlex® 2200 Anti-CCP Kit 510(k) Summary

510(k) Number K112810 Date Prepared: September 19, 2011

Introduction

Bio-Rad Laboratories hereby submits this Special 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This summary of 510(k) safety and effectiveness information provides detail as a basis for a determination of substantial equivalence for the BioPlex® 2200 Anti-CCP Kit.

Submitter name, address and contact

Submitter	Contact Person
Bio-Rad Laboratories, Inc BioPlex Division 5500 E. Second Street Benicia, CA 94510	Juang Wang Regulatory Affairs Representative Phone: (510)741-4609 Fax: (510)741-4650

Device name and Classification

Product Trade Name	BioPlex® 2200 Anti-CCP Kit
Common Name	Multi-Analyte Detection System –Anti-CCP IgG
Classification name	Antibodies, anti-Cyclic Citrullinated Peptide (CCP)
Device Class	Class II
Classification Panel	Immunology
Regulation Number	21 CFR 866.5775
Product Code	NHX

Legally Marketed Predicate Device

BioPlex® 2200 Anti-CCP Kit, k093954

Intended Use/Indications For Use

The BioPlex® 2200 Anti-CCP kit is a multiplex flow immunoassay intended for the semi-quantitative detection of IgG antibodies to Cyclic Citrullinated Peptide (CCP) in human serum or plasma (EDTA and sodium heparin). Detection of CCP antibodies is used as an aid in the diagnosis of rheumatoid arthritis and should be used in conjunction with other clinical findings and laboratory results.

The BioPlex® 2200 Anti-CCP kit is intended for use with the Bio-Rad BioPlex® 2200 System.

Device Description

The BioPlex® 2200 Anti-CCP kit uses multiplex flow immunoassay, a methodology that greatly resembles traditional EIA, but permits simultaneous detection and identification of many antibodies in a single tube. "CCP IgG" is an acronym for the detection of IgG antibodies to Cyclic Citrullinated Peptide.

One (1) population of fluorescent beads is coated with antigens associated with cyclic citrullinated peptide (CCP). The BioPlex® 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel and incubates the mixture at 37°C. After a wash cycle to remove unbound antibody, anti-human IgG conjugated to phycoerythrin is added and the mixture is incubated at 37°C. Excess conjugate is removed in another wash cycle and the washed beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the assay and control beads is determined by the fluorescence embedded in the surface of the bead and the amount of immobilized antibody is determined by the fluorescence of the anti-IgG reporter conjugate. Raw data are calculated in relative fluorescence intensity (RFI).

Three additional dyed beads, Internal Standard Bead (ISB), Serum Verification Bead (SVB) and Reagent Blank Bead (RBB) are present in each reaction mixture to verify detector response, the addition of serum or plasma to the reaction and the absence of significant non-specific binding. Refer to the BioPlex® 2200 System Operation Manual for more information.

The instrument is calibrated using a set of six (6) distinct calibrator vials, supplied separately by Bio-Rad Laboratories.

Similarities and Differences

Similarities

Feature	Modified Device
Intended Use/Indications For Use	No Change
Kit components	No Change
Technical Specifications	No Change
Fundamental Scientific Technology	No Change

Differences

The only difference of the BioPlex® 2200 Anti-CCP kit is to modify QC testing from each reagent pack to once per day as stated in the Instructions For Use (IFU) of the BioPlex®® 2200 Anti-CCP reagent kit.

Feature	Modified	Predicate
Frequency of Reagent Pack QC Testing	QC once per day or per new reagent pack lot	QC once per pack and per day

Summary of Design Control Activities

A Failure Mode and Effect Analysis (FMEA) was used to facilitate, capture, and quantify potential impacts of false positive or negative patient results. The Risk Priority Number (RPN) is a quantitative measure of the combined effects of severity, occurrence, and detection of potential risks. Specific mitigations are recommended that may include changes to the design or formulation if the RPN score exceeds a chosen threshold.

The Design Control Activities include Risk Analysis method to identify the verification and validation activities required, test used and acceptance criteria.

Based on the conclusion of the risk management report, the modified QC procedure fulfills the requirements of the specifications of the design control process. Therefore, the performance of the modified QC test frequency is substantially equivalent to the current cleared kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bio-Rad Laboratories
c/o Mr. Juang Wang
Regulatory Affairs Representative
BioPlex 2200 Division
5500 E. Second Street
Benicia, CA 94510

OCT 26 2011

Re: k112810
Trade/Device Name: Bio-Plex® 2200 Anti-CCP Kit
Regulation Number: 21 CFR § 866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II
Product Code: NHX
Dated: September 26, 2011
Received: September 27, 2011

Dear Mr. Wang:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication(s) for use

510(k) Number (if known): K112810

Device Name: BioPlex® 2200 Anti-CCP Kit

Indications for Use:

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The BioPlex 2200 Anti-CCP kit is intended for use with the Bio-Rad BioPlex 2200 system.

The BioPlex 2200 Anti-CCP Calibrator Set is intended for the calibration of the BioPlex 2200 Anti-CCP Reagent Pack.

The BioPlex 2200 Anti-CCP Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 instrument and BioPlex 2200 Anti-CCP Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 Anti-CCP Control Set has not been established with any other Anti-CCP assay.

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

(Please do not write below this line-Continue on another page of needed)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K112810