March 22, 2021

Gold Standard Diagnostics
Jennifer Roth
Vice President, Product Development
2851 Spafford St.
Davis, California 95618

Re: K203289
Trade/Device Name: Gold Standard Diagnostics Borrelia burgdorferi VlsE-OspC IgG/IgM ELISA Test Kit
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: November 4, 2020
Received: November 9, 2020

Dear Jennifer Roth:

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. 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 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. 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 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-devices/medical-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) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maria Ines Garcia, Ph.D.
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203289

Device Name
Gold Standard Diagnostics Borrelia burgdorferi VlsE-OspC IgG/IgM ELISA Test Kit

Indications for Use *(Describe)*

The Gold Standard Diagnostics Borrelia burgdorferi VlsE-OspC IgG/IgM ELISA Test Kit is intended as a qualitative test for the detection of IgG and IgM class antibodies to VlsE and OspC antigens from Borrelia burgdorferi sensu stricto in human serum from symptomatic patients or people suspected of having Lyme disease. When used as the first-tier screening test, positive and equivocal results must be confirmed through additional testing by one of the following methods:

• Standard two-tier test methodology (STTT) using an IgG and/or IgM blot testing following current interpretation guidelines, OR
• Modified two-tier test methodology (MTTT) using one or more of the following three ELISA based assays:
a. Gold Standard Diagnostics Borrelia burgdorferi IgG/IgM ELISA Test
b. Gold Standard Diagnostics Borrelia burgdorferi IgG ELISA Test
c. Gold Standard Diagnostics Borrelia burgdorferi IgM ELISA Test
The assay can also be used as a second-tier confirmation test using the MTTT methodology when used with one or more of the following three ELISA based assays:
a. Gold Standard Diagnostics Borrelia burgdorferi IgG/IgM ELISA Test
b. Gold Standard Diagnostics Borrelia burgdorferi IgG ELISA Test
c. Gold Standard Diagnostics Borrelia burgdorferi IgM ELISA Test
Positive test results by either the STTT or MTTT methodology are supportive evidence for the presence of antibodies and exposure to Borrelia burgdorferi, the cause of Lyme disease. A diagnosis of Lyme disease should be made based on the presence of Borrelia burgdorferi antibodies, history, symptoms, and other laboratory findings.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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