July 13, 2023

ZEUS Scientific
Mark Kopnitsky
Chief Scientific Officer
200 Evans Way
Branchburg, New Jersey 08876

Re: K230863
Trade/Device Name: ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System; ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Control Kit
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR, QCH
Dated: March 27, 2023
Received: March 29, 2023

Dear Mark Kopnitsky:

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,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230863

Device Name

ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System
ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Control Kit

Indications for Use *(Describe)*

The ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System uses chemiluminescent immunoassay (CLIA) technology for the qualitative detection of IgG/IgM antibodies to *Borrelia burgdorferi* in human serum. This assay is intended for use on samples from patients with signs and symptoms consistent with or patients suspected of having Lyme disease to assess the presence of IgG/IgM antibodies.

Positive results with the ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System should be supplemented with additional testing with a Standard two-tier test (STTT) methodology using an IgG and/or IgM *Borrelia burgdorferi* immunoblot assay following current guidelines.

Positive supplemental results are supportive evidence of the presence of antibodies and exposure to *Borrelia burgdorferi* and may be used along with patient history, symptoms and other laboratory data to support a clinical diagnosis of Lyme disease.

Negative results by the ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System should not be used to exclude Lyme disease. The test must be performed on the ZEUS Solinas instrument.

The ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Control Kit is intended for use as assayed quality control samples to monitor the performance of the ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Test System. The performance characteristics of the ZEUS Solinas Borrelia VlsE1/pepC10 IgG/IgM Control Kit have not been established for any other assays or instrument platforms.

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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