October 12, 2022

Roche Diagnostics
Cynthia Aker
Regulatory Affairs Principal
9115 Hague Road
PO Box 50416
Indianapolis, Indiana 46250

Re: K220924
Trade/Device Name: Elecsys HSV-2 IgG (08948887160)
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes simplex virus serological assays
Regulatory Class: Class II
Product Code: MYF
Dated: March 29, 2022
Received: March 31, 2022

Dear Cynthia Aker:

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 Garcia, Ph.D.
Assistant Director
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.

Submission Number *(if known)*

Device Name

Elecsys HSV-2 IgG (08948887160)

Indications for Use *(Describe)*

Immunoassay for the in vitro qualitative determination of IgG class antibodies to HSV-2 in human serum and lithium-heparin plasma, K2-EDTA plasma, and K3-EDTA plasma. The test is intended for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-2.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.
This test is not FDA-cleared for screening blood or plasma donors.
The performance of this assay has not been established for use in a pediatric population, neonates, or immunocompromised patients or for use at point-of-care facilities.

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

Prepared on: 2022-09-26

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Roche Diagnostics
Applicant Address	9115 Hague Road PO Box 50416 Indianapolis IN 46250 United States
Applicant Contact Telephone	1-463-336-2138
Applicant Contact	Mrs. Cynthia Aker
Applicant Contact Email	cynthia.aker@roche.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Elecsys HSV-2 IgG (08948887160)
Common Name	Herpes simplex virus serological assays
Classification Name	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2
Regulation Number	866.3305
Product Code	MYF

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K121895	Elecsys HSV-2 IgG	MYF

Device Description Summary 21 CFR 807.92(a)(4)

The Elecsys HSV-2 IgG immunoassay makes use of a sandwich test principle using biotinylated recombinant HSV-2-specific antigens and HSV-2-specific recombinant antigens labeled with a ruthenium complex. The Elecsys HSV-2 IgG immunoassay is intended for the qualitative determination of IgG class antibodies to HSV-2 in human serum and plasma to aid in the presumptive diagnosis of HSV-2 infection. It is intended for use on the cobas e immunoassay analyzers.
Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by
calibration.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Immunoassay for the in vitro qualitative determination of IgG class antibodies to HSV-2 in human serum and lithium-heparin plasma, K2-EDTA plasma, and K3-EDTA plasma. The test is intended for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection. The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-2.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.
This test is not FDA-cleared for screening blood or plasma donors.
The performance of this assay has not been established for use in a pediatric population, neonates, or immunocompromised patients or for use at point-of-care facilities.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Elecsys HSV-2 IgG (updated assay Mat. No. 08948887160) is substantially equivalent to Elecsys HSV-2 IgG, cleared under K121895.

The intended use of Elecsys HSV-2 IgG was updated to remove analyzers that are no longer supported for use with Roche assays. The intended use was also updated to add the following sentence: "The test results may not determine the state of active lesions or associated disease manifestations, particularly for primary infection."
The indications for use of the Elecsys HSV-2 IgG did not change from the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Roche Diagnostics has updated the current Elecsys HSV-2 IgG assay in order to improve the biotin tolerance from < 70 ng/mL to ≤ 1200 ng/mL and to reduce streptavidin interference. A technical solution was implemented by adding an anti-biotin antibody to one of the reagents, which allows depletion of biotin in patient samples by binding free biotin, and by adding a streptavidin interference reducing agent to enhance the streptavidin tolerance. No other technological characteristics were changed. The information submitted in this Premarket Notification supports a substantial equivalent decision.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)