January 4, 2023

Roche Diagnostics
Bin Sun
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, Indiana 46250

Re: K221693
Trade/Device Name: Elecsys Anti-HCV II (08837031190)
Regulation Number: 21 CFR 866.3169
Regulation Name: Hepatitis C Virus Antibody Tests
Regulatory Class: Class II
Product Code: MZO
Dated: June 9, 2022
Received: June 10, 2022

Dear Bin Sun:

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 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

Elecsys Anti-HCV II (08837031190)

Indications for Use *(Describe)*

Immunoassay for the in vitro qualitative detection of antibodies to hepatitis C virus (HCV) in human adult and pediatric (ages 18 months through 21 years) serum and plasma (potassium EDTA, lithium heparin, sodium heparin, and sodium citrate). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

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.

510(k) Summary

Prepared on: 2022-06-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Roche Diagnostics
Applicant Address	9115 Hague Road Indianapolis IN 46250 United States
Applicant Contact Telephone	317-292-3781
Applicant Contact	Mr. Bin Sun
Applicant Contact Email	bin.sun.bs2@roche.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Elecsys Anti-HCV II (08837031190)
Common Name	Hepatitis C virus antibody tests
Classification Name	Assay, Enzyme Linked Immunosorbent, Hepatitis C Virus
Regulation Number	866.3169
Product Code	MZO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
P140021	Elecsys Anti-HCV II Immunoassay	MZO

Device Description Summary

21 CFR 807.92(a)(4)

Immunoassay for the in vitro qualitative detection of antibodies to hepatitis C virus (HCV) in human adult and pediatric (ages 18 months through 21 years) serum and plasma (potassium EDTA, lithium heparin, sodium heparin, and sodium citrate). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

The Elecsys Anti-HCV II Immunoassay employs "ECLIA" technology and is a qualitative serologic, two step sandwich assay. The assay detects total antibodies to HCV in serum and plasma samples. The total duration of the assay is 18 minutes. The basic device methodology is as follows:
1. 1st incubation: 50 µL of sample, 55 µL of a reagent containing biotinylated HCV antigens, and 55 µL of a reagent containing HCV antigens labeled with a ruthenium complex react to form a sandwich complex.
2. 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
3. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of a voltage to the electrode then induces chemiluminescent emission, which is measured by a photomultiplier.
4. Results are determined automatically by the Elecsys software by comparing the electrochemiluminescence signal obtained from the sample with the cut-off value obtained by the anti-HCV calibration.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Immunoassay for the in vitro qualitative detection of antibodies to hepatitis C virus (HCV) in human adult and pediatric (ages 18 months

through 21 years) serum and plasma (potassium EDTA, lithium heparin, sodium heparin, and sodium citrate). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

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

Elecsys Anti-HCV II (updated assay, Mat. No. 08837031190) is substantially equivalent to Elecsys Anti-HCV II, approved under P140021.

The intended use of Elecsys Anti-HCV II was updated to remove analyzers that are no longer supported for use with Roche assays. The indications for use of updated Elecsys Anti-HCV II assay did not change from the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Roche Diagnostics has updated the current Elecsys Anti-HCV II assay in order to improve the biotin tolerance from ≤ 44 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)

1. Precision
The precision of the Elecsys Anti-HCV II assay was evaluated on one cobas e 601 immunoassay analyzer with one reagent lot. The protocol consisted of testing 2 aliquots of each of two levels of controls and 5 human serum samples per run, 2 runs per day for 12 days. The samples were run in randomized order on the analyzer. Repeatability and Intermediate imprecision were calculated according to CLSI EP05-A3 including the 95% confidence interval. All predefined acceptance criteria was met for the precision experiments.

2. Biotin Interference
The effect on measuring of analyte in the presence of biotin using the Elecsys Anti-HCV II assay was determined using three serum samples (negative, low positive and moderate positive) with three lots according to CLSI EP07-A3 Appendix A.
Unique negative serum was used for negative samples. Low positive and moderate positive samples were each prepared from unique negative serum spiked with unique anti-HCV positive serum. Samples were divided, and one part of each sample was spiked with the interfering endogenous substance and used as the "interference pool." Another part of the sample was spiked with the same volume of solvent as the interfering endogenous substance (without interfering substance) and used as the related "dilution pool."
A series of 17 dilution steps were prepared by mixing the interference pools and the related dilution pools.
The mean recovery (absolute deviation or percent recovery) was calculated for each sample compared to the expected value.
No biotin interference was observed up to 2520 ng/mL. The biotin claim in the method sheet will be set to 1200 ng/mL.

3. Method Comparison to Predicate
A method comparison study was performed to demonstrate equivalency between the performance of the current Elecsys Anti-HCV II assay and the biotin-updated Elecsys Anti-HCV II assay on one cobas e 601 analyzer.
A total of 219 samples were measured with one reagent lot of the current Elecsys Anti-HCV II assay and three different reagent lots of the biotin-updated Elecsys Anti-HCV II assay in single determination on the cobas e 601 analyzer. Results are presented in a 3x3 table. Positive Agreement and Negative Agreement between the current and updated assay were calculated. The resulting data support the equivalence of the current non-biotin and biotin-updated assay.

4. Stability
The stability studies and acceptance criteria have been reviewed and found to be acceptable. The stability data supports Roche Diagnostic's claims as reported in the package labeling.

On-board reagent stability for the Elecsys Anti-HCV II assay was tested on one cobas e 601 analyzer. Elecsys Anti-HCV II reagent kits can be stored on-board the analyzers for up to 31 days.

Lot calibration frequency for the Elecsys Anti-HCV II was tested on one cobas e 601 analyzer. The study confirm calibration stability of one month (28 days) with multiple kits from the same reagent lot. Calibrations of an Elecsys Anti-HCV II reagent lot is recommended every 4 weeks when using the same reagent lot.

Real-time stability was tested on one cobas e 601 analyzer. Data supporting a shelf-life of 12 months.

Not Applicable