DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Roche Diagnostics, Inc.
Linda McCammack, MT(ASCP)
Regulatory Program Manager
9115 Hague Road
Indianapolis, IN 46250

December 23, 2016

Re: P160019
Trade/Device Name: Elecsys Hbsag II, Elecsys HBsAg Confirmatory Test, and PreciControl HBsAg II
Filed: July 1, 2016
Amended: July 20, 2016, August 26, 2016, August 26, 2016, September 06, 2016, September 29, 2016, December 1, 2016
Product Code: LOM

Dear Ms. McCammack:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Elecsys Hbsag II, Elecsys HBsAg Confirmatory Test, and PreciControl HBsAg II. This device is indicated for:

Elecsys HBsAg II
Immunoassay for the in vitro qualitative detection of hepatitis B surface antigen (HBsAg) in human adult and pediatric (2 to 21 years of age) serum and plasma (sodium heparin, lithium heparin, K2 EDTA, sodium citrate). Assay results, in conjunction with other serological and clinical information, may be used for the laboratory diagnosis of individuals at risk for infection with HBV or with signs and symptoms of hepatitis. In addition, this assay may be used to screen for hepatitis B infection in pregnant women to identify neonates at high risk of acquiring HBV during the perinatal period.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas e 601 immunoassay analyzer.

Elecsys HBsAg Confirmatory Test
For Elecsys HBsAg Confirmatory Test used with Elecsys HBsAg immunoassay:
Immunoassay for in vitro qualitative confirmation of the presence of hepatitis B surface antigen in human serum and plasma (sodium heparin, K3 EDTA, sodium citrate) samples repeatedly reactive when tested with the Elecsys HBsAg immunoassay. This assay is intended for use on the Elecsys and cobas e immunoassay analyzers.

For Elecsys HBsAg Confirmatory Test used with Elecsys HBsAg II:
Immunoassay for in vitro qualitative confirmation of the presence of hepatitis B surface antigen in human serum and plasma (sodium heparin, lithium heparin, K2 EDTA, sodium citrate) samples repeatedly reactive when tested with Elecsys HBsAg II. This assay is intended for use on the cobas e 601 immunoassay analyzer.

PreciControl HBsAg II
PreciControl HBsAg II is used for quality control of the Elecsys HBsAg II immunoassay on the cobas e 601 immunoassay analyzer. The performance of PreciControl HBsAg II has not been established with any other HBsAg assay.

We are pleased to inform you that the PMA is approved. You may continue commercial distribution of the device upon receipt of this letter.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at twelve (12) months for the Elecsys HBsAg II, nine (9) months for the Elecsys HBsAg Confirmatory Test and sixteen (16) months for the PreciControl HBsAg II when the reagents are stored at 2 to 8^{o}C. This is to advise you that the protocols you used to establish the expiration dating for the Elecsys HBsAg II and PreciControl HBsAg II are considered approved protocols for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the

Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Laura Ulitzky at 240-402-7437 or Laura.Ulitzky@fda.hhs.gov.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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