



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

Siemens Healthcare Diagnostics, Inc.
Ingrid Mehlhorn, Ph.D.
RA Technical Specialist 4
P.O. Box 2466
Berkeley, California 94702-2466

March 14, 2017

Re: P160016

Trade/Device Name: VERSANT[®] HCV Genotype 2.0 Assay (LiPA)
VERSANT[®] HCV Amplification 2.0 Kit (LiPA)
VERSANT[®] HCV Control 2.0 Kit (LiPA)
VERSANT[®] Sample Preparation 1.0 Reagents

Filed: June 7, 2016

Amended: June 22, 2016, July 1, 2016, October 6, 2016

Product Code: OBF

Dear Dr. Mehlhorn:

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 your HCV genotyping device consisting of the following: VERSANT[®] HCV Genotype 2.0 Assay (LiPA), VERSANT[®] HCV Amplification 2.0 Kit (LiPA), VERSANT[®] HCV Control 2.0 Kit (LiPA), and VERSANT[®] Sample Preparation 1.0 Reagents. This device is indicated for:

VERSANT[®] HCV Genotype 2.0 Assay (LiPA)

The VERSANT[®] HCV Genotype 2.0 Assay (LiPA) is a line probe assay, for *in vitro* diagnostic use, which identifies Hepatitis C virus (HCV) genotypes 1 to 6 and subtypes 1a and 1b in human serum or plasma (K₂EDTA, ACD-A CPD, and CPDA) samples.

The VERSANT[®] HCV Genotype 2.0 Assay (LiPA) is intended to be used as an aid in the management of patients with chronic HCV infection to guide the selection of antiviral treatment.

The VERSANT[®] HCV Genotype 2.0 Assay (LiPA) is not approved for use as a donor screening test for HCV or as a diagnostic test to confirm the presence of HCV.

VERSANT[®] HCV Amplification 2.0 Kit (LiPA)

The VERSANT[®] HCV Amplification 2.0 Kit (LiPA) is designed for use with the VERSANT[®] HCV Genotype 2.0 Assay (LiPA) and the VERSANT[®] HCV Control 2.0 Kit (LiPA) products. The HCV Amplification 2.0 kit is for *in vitro* diagnostic use for reverse transcription and amplification of the 5' untranslated region (5'UTR) and core region of the Hepatitis C Virus (HCV) genome.

VERSANT[®] HCV Control 2.0 Kit (LiPA)

The VERSANT[®] HCV Control 2.0 Kit (LiPA) is designed for use with the VERSANT[®] HCV Amplification 2.0 Kit (LiPA) and the VERSANT[®] HCV Genotype 2.0 Assay (LiPA) products.

The VERSANT[®] HCV Control 2.0 Kit (LiPA) is for *in vitro* diagnostic use to monitor the performance of all steps of the VERSANT[®] HCV Genotype 2.0 assay.

VERSANT[®] Sample Preparation 1.0 Reagents

The VERSANT[®] Sample Preparation 1.0 Reagents Kit is intended to be used, along with the VERSANT[®] kPCR Molecular System Sample Preparation module (SP Module), for the isolation and purification of nucleic acids for *in vitro* diagnostic applications. The product is intended for use by laboratory professionals trained in molecular biology techniques.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

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 18 months for the VERSANT[®] HCV Genotype 2.0 Assay (LiPA) when stored at 2 to 8°C; 29 months for the VERSANT[®] HCV Amplification 2.0 Kit (LiPA) when stored at -20 ± 5°C; 24 months for the VERSANT[®] HCV Control 2.0 Kit (LiPA) when stored at 2 to 8°C; and 24 months for the VERSANT[®] Sample Preparation 1.0 Reagents when stored at 15-30°C (Box 1) and 2 to 8°C (Box 2). This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol 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 Kathleen Whitaker, Ph.D., at 301-796-6208 or Kathleen.Whitaker@fda.hhs.gov.

Sincerely,

Uwe Scherf -S

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health