4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Siemens Healthcare Diagnostics, Inc. (Siemens), for the ADVIA Centaur Zika test. FDA revoked this Authorization on July 17, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), in consideration of the premarket notification submission submitted to FDA by Siemens for the ADVIA Centaur Zika test that was determined to be substantially equivalent to a legally marketed class II predicate device on July 17, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of July 17, 2019.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3), as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On September 18, 2017, FDA issued an EUA to Siemens, for the ADVIA Centaur Zika test, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the *Federal Register* on November 17, 2017 (82 FR 54361), as required by section 564(h)(1) of the FD&C Act. In response to requests from Siemens, the EUA was amended on November 16, 2017, and April 18, 2019. Subsequently, on May 23, 2019, FDA classified a de novo application for a generic Zika virus serological reagents device as Class II (special controls) under product code QFO (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf). Under section 564(g)(2) of the FD&C Act, the Secretary of Health and Human Services may revoke an EUA if, among other things, the criteria for issuance are no longer met.

II. EUA Criteria for Issuance No Longer Met

On July 17, 2019, FDA revoked the EUA for Siemens' ADVIA Centaur Zika test because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act,

an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. FDA has determined that the criteria for issuance of such authorization under section 564(c)(3) of the FD&C Act are no longer met because Siemens' ADVIA Centaur Zika test was determined on July 17, 2019, to be substantially equivalent to a legally marketed class II predicate device with the generic name "Zika virus serological reagents" (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191578.pdf). As such, FDA concluded that there is an adequate, approved, and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the FD&C Act and accordingly revoked the Authorization pursuant to section 564(g)(2)(B) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at https://www.regulations.gov/.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Siemens' ADVIA Centaur Zika test. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

July 17, 2019

Matthew Gee, M.Sc.
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591

Dear Mr. Gee:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA170005) for emergency use of Siemens Healthcare Diagnostics Inc.'s ("Siemens") ADVIA Centaur Zika test, issued on September 18, 2017, and amended on November 16, 2017, and April 18, 2019.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. Siemens submitted a premarket submission to FDA for the ADVIA Centaur Zika test (K191578) that was determined to be substantially equivalent to a legally marketed Class II predicate device, classified under 21 CFR 866.3935, with the generic name "Zika virus serological reagents," on July 17, 2019. FDA has concluded "that this is an adequate, approved[1], and available alternative for diagnosing Zika virus infection for purposes of section 564(c)(3) of the Act."

Accordingly, FDA revokes EUA170005 for emergency use of the ADVIA Centaur Zika test, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the ADVIA Centaur Zika test that was authorized by FDA for emergency use under EUA170005 is no longer authorized by FDA.

[1] In the context of section 564 of the Act, the term "approved" refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

FDA does not have concerns with the use of any remaining inventory of the ADVIA Centaur Zika test that was distributed prior to revocation of the EUA, when such product is used in conjunction with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. FDA encourages the relabeling of any product already manufactured, but not distributed prior to the revocation of the EUA, with the ADVIA Centaur Zika test labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578. Importantly, the ADVIA Centaur Zika test product for which FDA had issued an EUA and the device cleared under K191578 are manufactured under the same quality system. Siemens should instruct customers who have remaining ADVIA Centaur Zika test EUA product inventory to either use their EUA product in combination with the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578, or to work with Siemens to replace the EUA product with the device cleared under K191578. FDA encourages Siemens to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of the EUA revocation and provide access to the labeling associated with the device cleared on July 17, 2019, under premarket notification submission K191578.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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