UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 16, 2020**

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**0-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

555 Wireless Blvd. Hauppauge, NY 11788
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(631) 924-1135**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On June 16, 2020, we received a letter from the U.S. Food and Drug Administration, or FDA, notifying us that the FDA was revoking the Emergency Use Authorization, or EUA, granted in April 2020 with respect to our DPP COVID-19 System, which consists of our serological test for COVID-19 and one of our Micro Reader analyzers. As a result of this decision by the FDA, we may no longer distribute the DPP COVID-19 System.

The DPP COVID-19 System was one of the first antibody tests authorized by the FDA during the COVID-19 public health emergency. Based on the information that we submitted to the FDA at the time of authorization, the FDA concluded that our test system met the applicable "may be effective" standard for an EUA.

In its letter of June 16, 2020, the FDA stated that it had decided to revoke the EUA for the DPP COVID-19 System due to performance concerns regarding the sensitivity and specificity of our test system. According to the FDA, an independent evaluation of our test system by the National Institutes of Health's National Cancer Institute, as well as other independent evaluations, showed (a) our test system generated a higher rate of false results than expected under our initial EUA request and our authorized labeling and (b) it is not reasonable to believe that our test system may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of our test system outweigh its known and potential risks.

We intend to continue working with the FDA with respect to the modification of the DPP COVID-19 System and of the revocation of the EUA for our test system.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Dated: June 17, 2020

By: /s/ RICHARD EBERLY
Chief Executive Officer and President