May 29, 2018

Mr. Josh Rosenthal
Managing Director
Tiger Medical, Inc.
27 Selvage Street
Irvington, NJ 07111-4722

Dear Mr. Rosenthal:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your Internet website http://www.tigermedical.com and your sale and distribution of the Alere Determine™ HIV-1/2 Ag/Ab Combo test kits from your website. Copies of the pertinent Internet website pages are enclosed for your reference.

Under the relevant parts of section 201(h) of the Act, 21 U.S.C. § 321(h), Alere Determine™ HIV-1/2 Ag/Ab Combo test kits are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body and do not achieve their primary intended purposes through chemical action within or on the body. Under section 520(e) of the Act, 21 U.S.C. § 360j(e), FDA may by regulation restrict the sale, distribution, or use of a device, "if, because of its potentiality for harmful effect or the collateral measures necessary to its use . . . there cannot otherwise be reasonable assurance of its safety and effectiveness."

When FDA approved the Alere Determine™ HIV-1/2 Ag/Ab Combo test kits on August 9, 2013, the agency restricted the sale and distribution of the device to prescription use in accordance with 21 C.F.R. § 801.109 and under section 515(d)(1)(B)(ii) of the Act, 21 U.S.C. § 360e(d)(1)(B)(ii). One of the conditions of 21 C.F.R. § 801.109(a)(2) states that such device "is to be sold only to or on the prescription or other order" of a practitioner such as a physician, "for use in the course of his professional practice." Among other conditions to approval, FDA required that the device labeling specify that "sale of Alere Determine™ HIV-1/2 Ag/Ab Combo is restricted to clinical laboratories that have an adequate quality assurance program, including planned and systematic activities that provide adequate confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional material."

CBER has learned that the sale of Alere Determine™ HIV-1/2 Ag/Ab Combo test kits by Tiger Medical, Inc. (Tiger Medical) through http://www.tigermedical.com, is not restricted in accordance with 21 C.F.R. § 801.109(a)(2). Although a "Special Note" on

your website states, “This product can only be purchased by a Medical Facility or Licensed Physician,” Tiger Medical is not limiting the sale or distribution of the Alere Determine™ HIV-1/2 Ag/Ab Combo test kits to such customers, nor do you require a prescription or other order of a practitioner.

The Alere Determine™ HIV-1/2 Ag/Ab Combo test kits sold by Tiger Medical, through http://www.tigermedical.com, are misbranded under section 502(q)(2) of the Act, 21 U.S.C. § 352(q)(2), in that they are restricted devices that are sold and distributed in violation of regulations prescribed under section 520(e) of the Act, including 21 C.F.R. § 801.109. Because these devices do not meet the conditions in 21 C.F.R. § 801.109, they also are not exempt from section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). As such, the Alere Determine™ HIV-1/2 Ag/Ab Combo test kits sold by Tiger Medical, through http://www.tigermedical.com, are misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use. FDA hereby requests that Tiger Medical immediately cease the sale and distribution of Alere Determine™ HIV-1/2 Ag/Ab Combo test kits on http://www.tigermedical.com until the sale and distribution of the devices are restricted in accordance with the device’s approval; section 515(d)(1)(B)(ii) of the Act, 21 U.S.C. § 360e(d)(1)(B)(ii); and the regulations prescribed under section 520(e) of the Act, including 21 C.F.R. § 801.109.

The violations set forth in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your marketing, sale, and distribution of Alere Determine™ HIV-1/2 Ag/Ab Combo test kits comply with all applicable requirements of the Act and its implementing regulations.

If you have any questions regarding this matter, you may contact Anna M. Flynn, Consumer Safety Officer in CBER’s Office of Compliance and Biologics Quality, at (240) 402-9156.

Sincerely,

/s/

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research