July 10, 2018

UPS EXPRESS MAIL

Ycellbio Medical Co., Ltd.
Rm 403, 52 Janghan-ro, Dongdaemungu
Seoul, 02643, South Korea

To Whom It May Concern:

The Food and Drug Administration (FDA) reviewed your Internet website, https://www.ycellbio.com/en/index.php, which states that your Y-PRP System (hereinafter, Ycellbio kit) "facilitates separating and harvesting 'pure sources of concentrated platelets'" from "a small sample of blood at the patient's point of care." According to your website, the Ycellbio kit "produces a maximum of platelet concentration from a minimum of blood volume (15ml blood volume)," and its "tornado technique maximizes harvest of [platelet rich plasma (PRP)] excluding [red blood cells]." Copies of the pertinent Internet website pages are enclosed for your reference.

Claims on your website and downloadable Ycellbio PRP brochure demonstrate that your Ycellbio kit, whether used with or without the centrifuge you also market on your website, is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) in part because it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or function of the body of man or other animals (21 U.S.C. 321(h)).

For example, your website and brochure describe your Ycellbio kit as an "Optimal System of Regenerative Therapy" that "enables physicians to get the most effective and enriched PRP," which the website indicates may be used for a variety of purposes, including Dermatology (e.g., skin regeneration), General Surgery, Chronic Wounds, and Ophthalmology. Additionally, your website makes claims such as:

- "Y-PRP system has been developed for optimal PRP separation and extraction, adding creative functions to produce high concentration of platelets, increase efficacy, and simplify the process.

  Its innovative technology enables physicians to get the most effective and enriched PRP that shows great performance defined in its clinical studies."

- "The Ycellbio PRP separation system is designed to be used for the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care."

The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. This premarket review process promotes the public health by, among other things, helping to ensure that devices are safe and effective for each intended use, which in turn helps prevent patient harm and ensure that devices deliver the expected benefits to patients.

In a letter dated March 23, 2016, FDA notified your firm that the Ycellbio kit is "not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Special Controls), or to another device found to be substantially equivalent through the 510(k) process." In that same letter, FDA further stated that "this device is classified by statute into class III (Premarket Approval), under Section 513(f) of [the Act]" and "[a]ny commercial distribution of this device prior to approval of a [premarket approval application (PMA)], or the effective date of any order by [FDA] re-classifying this device into class I or II, would be a violation of the Act." We note that FDA has not issued any order re-classifying this device into class I or II.

A review of our databases found that your firm has not obtained premarket approval or clearance for your Ycellbio kit, and you have not received an investigational device exemption from premarket approval.[1] Nevertheless, your Ycellbio kit appears to be available for purchase worldwide, including to buyers in the United States. For example, the "Contact" form on your website allows prospective customers to select the statement, "I want to purchase Ycellbio PRP" and has an entry line for "Country," which indicates the kit is available to customers in the United States. Because you do not have marketing approval or clearance from FDA for your Ycellbio kit, marketing this product in the United States would violate the Act.

For the above reasons, your Ycellbio kit, whether sold with or without the centrifuge also promoted on your website, is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved PMA in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational

[1] We note that you submitted device listing information indicating your "Ycellbio kit" is a class I "Mixer, Blood Tube." Class I devices are those for which "general" controls alone are sufficient to provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(A). Most class I devices, but not all, are exempt from premarket clearance requirements pursuant to 21 U.S.C. 360(l). Your Ycellbio kit is not a class I Mixer, Blood Tube and is not exempt from the premarket clearance requirements; as FDA explained in its March 23, 2016 letter, the device is classified by statute into class III under section 513(f) of the Act, and an approved PMA is required before the device can be legally marketed, unless the device is reclassified.

device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). Additionally, the same device is misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because notice or other information respecting the device was not provided to FDA, as required by section 510(k) of the Act, 21 U.S.C. 360(k).
Finally, we note that your Ycellbio PRP brochure contains the FDA logo. The FDA logo is for the official use of FDA and not for use on private sector materials. Unauthorized use of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability.

Please be advised that this letter is not intended to be an all-inclusive list of potential violations. It is your responsibility to ensure that you and your products comply with all applicable laws and regulations.

If you have any questions regarding this matter, you may contact Steven Thurber, Consumer Safety Officer, Division of Case Management, Office of Compliance and Biologics Quality at (240) 402-2441. If you believe that your product is not in violation of the Act, include your reasoning and any supporting information for our consideration. Please be advised that only written communications are considered official.

Sincerely,

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