



Inspections, Compliance, Enforcement, and Criminal Investigations

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Warning Letters

ZYTO Technologies, Inc. 5/8/15

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ZYTO Technologies, Inc. 5/8/15



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal
Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
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May 8, 2015

WARNING LETTER

Vaughn R. Cook, CEO
ZYTO Technologies, Inc.
387 South 520 West, Suite 200
Lindon, UT 84042

VIA UPS

Ref # DEN-15-10 WL

Dear Mr. Cook:

During an inspection of your firm located at 387 South 520 West, Suite 200, Lindon, Utah, on November 14, 2014 through December 3, 2014, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures the ZYTO Hand Cradle, a Class II galvanic skin response measurement device, and the ZYTO Laser and ZYTO Tower, which are intended to be used as accessories with the ZYTO Hand Cradle. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products 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 are intended to affect the structure or function of the body of man or other animals.

During the inspection, we observed your firm's manufacturing and distribution activities pertaining to the ZYTO Hand Cradle galvanic skin response device. We also collected labels, labeling, and promotional materials for the ZYTO Hand Cradle and supporting accessories. This inspection concluded on December 3, 2014 with the issuance of an eleven item FDA Form 483, Inspectional Observations.

We acknowledge receipt of your firm's letter dated December 22, 2014, responding to the FDA Form 483. We have determined that your firm's response was inadequate in failing to address the concerns discussed with your firm during the inspection pertaining to your firm's labeling and promotion of its products.

The FDA has reviewed pertinent information obtained during the inspection and reviewed your company's website. We have determined that the ZYTO Hand Cradle is adulterated under section

501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g), for the device as described and marketed. The ZYTO Hand Cradle is also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered into interstate commerce for commercial distribution this device with major changes or modifications to the intended use without submitting a new premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(ii).

Specifically, the ZYTO Hand Cradle was cleared under K111308 with the following intended use: “the measurement of galvanic skin response (GSR).” However, your firm’s promotion of the device represents a major change or modification to its intended use, for which your firm lacks clearance or approval. Examples include:

- The www.zyto.com website provides that “Clinical studies have compared ZYTO scan reports with results produced by generally accepted diagnostic methods. One pilot study conducted in Beijing China compared the results of a four-minute ZYTO scan to a two-day diagnostic workup on several hundred patients. The results showed a high correlation.”
- The “How ZYTO TECHNOLOGY WORKS” brochure states, “ZYTO technology enables a computer to understand your body. The Hand Cradle measures your body’s galvanic skin response. ZYTO’s various software offerings take this input and interpret it in terms of what we call your biological preference...VSIs are representative of a wide range of things like foods, nutritional supplements, prescription medications, body organs and systems, and therapeutic treatments...ZYTO’s software indicates what is referred to as Biological Preference and Biological Aversion.”
- The “COMPASS Your Guide to Health” brochure states, “ZYTO’s technology measures your body’s responses to a specific library of nutritional products, asking your body which it prefers; this is called biocommunication.”
- The “Better Health at Your Fingertips...an introduction to ZYTO biocommunication” brochure states, “When your scan is complete, a report is generated that provides you and your healthcare provider with helpful information that was obtained. This report may provide insights that will prompt a closer look at specific organs and body systems, and explore your biological preference for medicine, nutritional supplements, and treatments you could benefit from. Biological preference simply means those stimuli your body responds most favorably to. Using this information, you and your healthcare provider can decide on a clinical strategy developed specifically for you, based on your body’s responses.”
- The “Incorporating ZYTO into your practice” practice manual booklet for ZYTO “Balance” provides that “The ZYTO Balance 5.0 is designed specifically to accomplish three objectives:
 - 1. To identify nutritional supplements that your patient shows a biological preference for.

- 2. To identify services offered in your practice for which your patient shows a biological preference...”
- The “Incorporating ZYTO into your practice” practice manual booklet for ZYTO “Select” provides that “General nutritional assistance biosurveys will help to identify your patient’s biological preference for the products you sell. Other biosurveys may provide you with information specific to disease, toxins or organs and body functions;”
- The user manual for ZYTO “Elite” provides that “There are many different biosurveys that you could run on a client during a session. For example, if you have a client complaining of seasonal allergies you could select a biosurvey that has been specifically designed for allergies. The allergy biosurvey would scan for and record your client’s responses to different allergen VSIs. The biosurvey could then scan for alternatives, VSIs that represent remedies, supplements, medications, or therapies.”

The promotion of the ZYTO Hand Cradle for use in diagnosing a disease or condition, predicting biological responses to a wide range of virtual stimuli including drugs and nutritional supplements, or determining whether someone responds to a specific allergen fall outside of the device’s cleared intended use to measure galvanic skin response and constitutes a major change or modification to the device’s intended use.

In addition, based on FDA’s review of the materials obtained during the inspection, we have determined that your firm is distributing the ZYTO Laser and ZYTO Tower without marketing clearance or approval. The ZYTO Laser and ZYTO Tower are intended to be used with the ZYTO Hand Cradle for the transmission, interpretation, and creation of virtual stimuli items (VSI). These VSIs are then added to the user’s library for “bio-communication” when using the ZYTO Hand Cradle. The ZYTO Laser and ZYTO Tower are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have approved PMAs in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or approved applications for IDEs under section 520(g) of the Act, 21 U.S.C. § 360j(g). The ZYTO Laser and ZYTO Tower are also misbranded under section 502(o) of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce these devices into commercial distribution as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency, 21 CFR 807.81(b). The kind of information your firm needs to submit in order to obtain approval or clearance for the devices is described on the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate the information your firm submits and decide whether your products may be legally marketed.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies may be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, including an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Food and Drug Administration, Denver District, P.O. Box 25087, (6th Ave. and Kipling Pkwy., DFC, Bldg 20), Denver, CO 80225-0087, Attention: Matthew R. Dionne, Pharm.D., Compliance Officer. Refer to the identification number DEN-15-10 WL when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact Dr. Dionne at (303) 236-3064.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your firm. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA Form 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's marketing and distribution practices. Your firm should investigate and determine the causes of the violations and take prompt actions to correct the violations to bring the products into compliance.

Sincerely,

/S/

LaTonya M. Mitchell
District Director

ZYTO Technologies Racks Up Warning Letter and 483

Aug. 14, 2015



Medical device maker ZYTO Technologies received an FDA warning letter May 8 for labeling and promotion issues that stemmed from a Dec. 3, 2014, 11-item Form 483 for numerous quality system deviations.

QS deviations cited in the 483 included not establishing corrective and preventive action procedures or design control procedures for the ZYTO hand cradle, a Class II skin measurement device, and the ZYTO laser and tower accessories.

The firm also did not establish design change procedures or procedures for receiving, reviewing and evaluating complaints. It also did not have procedures in place to establish whether the product conformed to specified requirements, nor were suppliers evaluated on their ability to meet specified requirements, according to the 483.

The firm also did not conduct risk analysis or quality audits for its products nor did it maintain a device master record or procedures for training and identifying training needs.

Following the firm's Dec. 22, 2014, response, the FDA sent a warning letter to the firm for labeling and promotion issues and for making major changes without submitting a new premarket notification to the FDA.

The FDA notes in the warning letter that the hand cradle was cleared to measure galvanic skin response, but that the firm was promoting the device for wider indications and citing clinical studies outside of the approved indication.

In response to the warning letter, the firm issued a statement that said it was working with the agency to "clarify and modify promotional language associated with the labeling of the ZYTO Hand Cradle."

The firm said the November 2014 inspection was its first FDA inspection, which covered all aspects of its manufacturing processes as well as all messaging relating to the ZYTO medical device.

“We welcome this input from the FDA,” said ZYTO President Kami Howard. “We have a strong desire to represent ZYTO products to our customers accurately and clearly. We have already addressed each specific issue raised by the FDA.”

Whether you need to convince the FDA to accept a predicate device in a simple 510(k) filing, make design changes or implement UDI across a family of high-risk implantable devices, there’s one thing all regulatory professionals need — the most up-to-date, latest FDA regulations available. Get out bestselling [Guide to FDA Medical Device Regulations](#) today!



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Biofeedback Device
better do Biofeedback
or you are in Trouble**