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MEMORANDUM

April 3, 2007

BY ELECTRONIC MAIL

TO: Mr. Thomas Ireland
President
AlternativeElectrodes.com, LLC

FROM: Neil F. O'Flaherty
Evan P. Phelps

RE: 510(k) Clearances and Off-Label Uses

The U.S. Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties. Generally speaking, the classification given to a generic type of device is based upon the risk the device poses to the patient or the user, and the level of regulatory control deemed necessary to "provide reasonable assurance of the safety and effectiveness of the device."¹ The underlying concept is that only the most risk-laden medical devices (those in Class III) should be subject to the most stringent level of FDA regulation. Class III devices must comply with the onerous premarket approval (PMA) requirement² and are the only devices "approved" by FDA.

¹ See, generally, 21 U.S.C. § 360c.

² "Pre-amendment" Class III devices – i.e., Class III devices that were marketed in the U.S. prior to the enactment of the Medical Device Amendments (May 28, 1976) – and devices that are substantially equivalent to pre-amendment Class III devices, are not presently required to go through the PMA approval process unless FDA has by regulation called for PMAs for the particular type of device. Instead, they can utilize the 510(k) process.

Moderate risk devices typically are classified into Class II.³ Examples of Class II devices include powered muscle stimulators, transcutaneous electrical nerve stimulators, cutaneous electrodes and electroconductive media. Unlike Class I devices, which usually are exempt from premarket scrutiny, Class II devices generally are subject to FDA's premarket review requirement known as a premarket notification or 510(k).⁴ Upon successful completion of the 510(k) process, Class II devices are considered "cleared" for marketing. FDA clears devices for marketing. FDA does not clear particular therapeutic or diagnostic procedures or regimens.

What does a 510(k) Clearance Mean?

A 510(k) is a comparative submission: In order to obtain 510(k) clearance to market a device, a 510(k) submitter must demonstrate that its device is "substantially equivalent" (SE) to a legally marketed "predicate" device. "Substantial equivalence" means:

the [510(k)] device has the same intended use as the predicate device and that [FDA] by order has found that the device—

- (i) has the same technological characteristics as the predicate device, or
- (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by [FDA]..., that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.⁵

Does FDA Test 510(k) Devices to Ensure They Are Safe and Effective?

FDA does not perform any testing to ensure that devices are safe and effective. Rather, the SE determination is made solely upon FDA's review of information provided by the device manufacturer. Therefore, any representation made or used by a device manufacturer that explicitly or by implication indicates that FDA has tested a medical device and found it safe and effective would be a false and misleading statement.⁶ Such statements misbrand⁷ the medical device in question, making its distribution illegal.⁸ Thus, if a manufacturer were to promote a device in a way that gives the impression that it is proven safe and effective through agency testing, the manufacturer would be violating FDA regulations.

Does FDA officially "approve" 510(k) devices?

As stated above, the only devices that are approved by FDA are Class III PMA devices. For this reason, among others, FDA regulations specifically state: "Any representation that creates an impression of official [FDA] approval of a device because of complying with the premarket notification [510(k)] regulations is misleading and constitutes

³ 21 U.S.C. § 360c(a)(1)(B).

⁴ Id.

⁵ 21 U.S.C. § 360(i)(A).

⁶ 21 U.S.C. § 352(a).

⁷ Id.

⁸ 21 U.S.C. § 331(a).

misbranding.”⁹ Therefore, statements that suggest 510(k) devices (e.g., electronic muscle stimulators, cutaneous electrodes) have been approved by FDA, clearly misbrand such devices pursuant to FDA regulations.¹⁰ Other examples of statements that could give the impression of official agency approval of a 510(k) device could include statements such as: “this device is part of a 510(k) cleared method for the treatment of dysphagia;” “this device has been reviewed and cleared to market by FDA;” and “this device is the only such device to receive 510(k) clearance from FDA.” Again, it is against the law to distribute a medical device that is misbranded.¹¹

Off-Label Promotion v. Off-Label Use

When a device receives 510(k) clearance, it may be promoted only for the indications for use that were cleared by FDA. For example, an electronic muscle stimulator may not be promoted for strengthening muscles if that indication for use of the device was not cleared as part of the device’s 510(k) submission. This type of “off-label” promotion on the part of the manufacturer misbrands¹² or adulterates¹³ a medical device.

However, it is only the manufacturer’s off-label promotion of medical devices that is prohibited by FDA. As a matter of law, FDA does not regulate the practice of medicine.¹⁴ Therefore, licensed health care practitioners are generally free to employ a cleared or approved medical device in any way they deem medically proper in a legitimate health care practitioner-patient relationship. This includes any off-label uses that would misbrand or adulterate the device were the device’s manufacturer to promote the device for such use.

Reporting of Suspected Illegal Device Promotion

In the event that a consumer or clinician believes that a device is being improperly promoted by its manufacturer, there are certain mechanisms for confidentially reporting such activities to FDA for review. Complaints regarding the suspected illegal promotion of medical devices may be reported to FDA by sending an e-mail to webcomplaints@ora.fda.gov. FDA has also established a website to enable the reporting of suspected illegal Internet marketing of medical products.¹⁵ Finally, consumers and clinicians may also send written complaints to FDA. These types of complaints are known as “Trade Complaints.” If possible, it is also advisable to include examples of the improper promotional materials with the Trade Complaint. Trade Complaints regarding the illegal promotion medical devices should be addressed to:

Director
Promotion and Advertising Policy Staff
Office of Compliance
Center for Devices and Radiological Health (HFZ-302)
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

⁹ 21 C.F.R. § 807.97.

¹⁰ Id.

¹¹ 21 U.S.C. § 331(a).

¹² 21 U.S.C. § 352(o).

¹³ 21 U.S.C. § 351(f)(1)(B).

¹⁴ 21 U.S.C. § 396.

¹⁵ <http://www.fda.gov/oc/buyonline/buyonlineform.htm>

Memorandum to Mr. Thomas Ireland
April 3, 2007
Page 4

Olsson, Frank and Weeda, P.C.

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We hope you find this memorandum useful and informative. If you have any questions or need additional information, please do not hesitate to contact us.

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