§ 870.2770. FDA has added a new product code, OAC, to § 870.2770 and includes the SONAMET Body Composition Analyzers (BOD POD and PEA POD) under it.

FDA believes that the petition lacks sufficient valid scientific evidence to allow FDA to determine that general controls would provide reasonable assurance of the safety and effectiveness of the impedance plethysmograph for its intended use. Therefore, the impedance plethysmograph shall be retained in class II.

VII. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Life Measurement Inc., for the reclassification of the SONAMET Body Composition Analyzers (BOD POD and PEA POD) devices, dated March 21, 2005.

Dated: June 25, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–12883 Filed 7–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0213]

Neurological Devices; Denial of Request for Change in Classification of Cutaneous Electrode

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by Scientific Laboratory Products LTD., to reclassify electroencephalogram (EEG) electrodes from class II to class I. The agency is denying the petition because the Scientific Laboratory Products LTD., failed to provide sufficient new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the devices. This document also summarizes the basis for the agency's decision.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4021.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976 (the 1976 Amendments)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments were class I (general controls); class II (performance standards); and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has done the following: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device type; and (3) published a final regulation classifying the device type. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless: (1) The device type is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act (21 U.S.C. 360c(e)). This section of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in sections 513(e) and 515(b)(2)(A)(iv) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). In addition, § 860.123(a)(6) (21 CFR 860.123(a)(6)) provides that a reclassification petition must include a ''full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification, and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device.'' (§ 860.123(a)(6).) The

''supporting data satisfying the requirements of § 860.7'' referred to is ''valid scientific evidence.''

For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Reclassification under SMDA

SMDA further amended the act to change the definition of a class II device. Under SMDA, class II devices are those devices which cannot be classified into class I because general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act). Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II into class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of September 4, 1979 (44 FR 51732), FDA issued a final rule classifying the cutaneous electrode into class II (21 CFR 882.1320). The preamble to the proposal to classify the device included the recommendation of the Neurological Device Classification Panel (the Panel). The Panel's recommendation, among other things, identified the following risks to health associated with the use of the device: (1) Burns, since poor design or incorrect application of the electrodes could result in skin burns when the device is used to apply stimulation and (2) toxic reactions, since materials or substances in the electrodes that are in contact with the skin could produce adverse reactions.

The panel recommended that cutaneous electrodes be classified as class II because the electrical properties of the device must be controlled to assure that, when physiological signals are recorded, they are adequately reproduced. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. Additionally, the panel recommended Class II to assure that only materials with known and acceptable properties are used in electrodes.

On May 31, 2005, FDA received a petition requesting that FDA reclassify electroencephalogram electrodes from class II to class I (Ref. 1). Under § 860.120(b) (21 CFR 860.120(b)), the reclassification of any device within a generic type of devices causes the reclassification of all substantially equivalent devices within that generic type of device.

IV. Device Description

The electroencephalogram electrode device is classified within the generic type of device cutaneous electrode (21 CFR 882.1320). FDA identifies cutaneous electrode as an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

V. FDA's Decision

After reviewing the reclassification petition, FDA has found that the petition contains insufficient valid scientific evidence to allow FDA to determine that general controls would provide reasonable assurance of the device's safety and effectiveness for its intended use. FDA, therefore, is denying the petition.

VI. Reasons for the Denial

FDA has determined that Scientific Laboratory Products LTD., has not presented sufficient new scientific information to support the requested change in classification of this device. According to § 860.120(b), the reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type. The petitioner has not provided any evidence to reclassify their own device or the generic cutaneous electrode device category.

FDA believes that the petition lacks sufficient valid scientific evidence to allow the agency to determine that general controls would provide reasonable assurance of the safety and effectiveness of the cutaneous electrode for its intended use. Therefore, the cutaneous electrode shall be retained in class II.

VII. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Scientific Laboratory Products LTD., for the reclassification of the electroencephalogram electrode device, dated May 16, 2005.

Dated: June 25, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–12882 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0233]

Draft Guidance for Industry on Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.'' Since FDA began accepting new drug application (NDA) and biologics license application (BLA) submissions in the common technical document (CTD) format, there has been much confusion regarding where within the CTD to include an integrated summary of effectiveness (ISE) and integrated summary of safety (ISS), both of which are required components of an NDA submission and recommended components of a BLA submission. This guidance informs applicants on where to place the ISE and ISS in the CTD. This guidance addresses specific FDA requirements not discussed in the ICH guidance for industry M4E: The CTD—Efficacy. This guidance is intended to improve application quality and consistency.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the