copy of ''Healthy People 2010'' at *http://www.health.gov/healthypeople*.

Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Authority and Regulations

This program is described in the CFDA at *http://www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of sections 301 and 405 of the PHS Act as amended (42 U.S.C. 241 and 284) and under federal regulations 42 CFR part 52 and 45 CFR parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement, dated October 1, 2006, (*http://www.hhs.gov/grantsnet/adminis/gpd/index.htm*).

Dated: June 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–12881 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0207]

Medical Devices; Cardiovascular Devices; Denial of Request for Change in Classification of Impedance Plethysmograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by Life Measurements Inc., to reclassify the SONAMET Body Composition Analyzers (BOD POD and PEA POD) from class II to class I. The agency is denying the petition because Life Measurements Inc., failed to provide sufficient new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the devices. This notice 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 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 (FDAMA) (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: (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, subpart E, 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 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. 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 § 560.7(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 the SMDA

The SMDA further amended the act to change the definition of a class II device. Under the 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 February 5, 1980 (45 FR 7930), FDA issued a final rule classifying the Impedance Plethysmograph into class II (§ 870.2770 (21 CFR 870.2770)). The preamble to the proposal to classify the device included the recommendation of the Cardiovascular 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) Cardiac arrhythmias or electrical shock—Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias and (2) Misdiagnosis—If the zero or calibration of the device is inaccurate or unstable, or if frequency response of the device is improper, the device can generate inaccurate diagnostic data. 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.

On May 25, 2005, FDA received a petition requesting that FDA reclassify SONAMET Body Composition Analyzers (BOD POD and PEA POD) 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.

The May 25, 2005, petition also requested that the SONAMET Body Composition Analyzers (BOD POD and PEA POD) be given their own product code because their devices are based on air displacement plethysmography technology, not impedance plethysmograph technology.

IV. Device Description

The SONAMET Body Composition Analyzers (BOD POD and PEA POD) are classified within the generic type of device impedance plethysmograph (§ 870.2770) and given the product code MNW. Both SONAMET Body Composition Analyzers were found substantially equivalent to class II devices under § 870.2770.

V. FDA's Decision

After reviewing the reclassification petition, FDA has found that the petition does not contain sufficient valid scientific evidence to support a determination that general controls would provide reasonable assurance of the devices' safety and effectiveness for their intended uses. Therefore, FDA is denying the reclassification request.

FDA did determine that both SONAMET Body Composition Analyzers are substantially equivalent to other legally marketed body composition analyzers classified under § 870.2770, product code MNW, the product code for body composition analysis devices. However, due to variations in the technology of impedance plethysmographs and displacement plethysmographs, FDA has given displacement plethysmographs for body composition their own product code under § 870.2770. FDA is adding a new product code, OAC, to § 870.2770 and updating the product code for the SONAMET Body Composition Analyzers (BOD POD and PEA POD) under § 870.2770. This new product code will be used to classify any plethysmograph device using air displacement for body composition analysis that is determined to be substantially equivalent.

VI. Reasons for the Denial

FDA has determined that Life Measurement Inc., has not presented new scientific information sufficient to support the requested change in classification (class II to class I) of their devices. 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.

Life Measurement Inc., has (1) not provided sufficient evidence to reclassify their own devices and has (2) not provided the required elements of a reclassification petition to down-classify any or all other body composition analyzers of different technology under § 870.2770.

The petitioner's accompanying data refers only to one of Life Measurement Inc.'s two devices proposed for reclassification, the BOD POD. No new information on the PEA POD was provided. The PEA POD, which is intended for use in newborns and infants, is the more critical of the two devices. While the patient population being tested with the BOD POD can terminate usage of the device during measurement, the patient population using the PEA POD (infants) is helpless to intervene in any aspect of the device operation if safety is suddenly compromised.

All the evidence presented by the petitioner is anecdotal and not sufficient to support the conclusion that general controls would provide reasonable assurance of the safety and effectiveness of this type device, including the Life Measurement Inc., devices. No published studies have been provided specifically targeting safety regarding devices of this type, including the Life Measurement Inc., devices, to support the petition. Additionally, the petitioner has not provided any information about adverse events or time of use for either of these devices.

However, Life Measurement Inc.'s differing technology for body composition is a legitimate basis for consideration of a new product code. FDA agrees that variations in the technology of impedance plethysmographs and air displacement plethysmographs for body composition analysis warrant FDA's assigning air displacement plethysmographs for body composition analysis (e.g., BOD POD) their own product code under

§ 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