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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2011–N–0361]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Wireless Air-Conduction Hearing Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the wireless air-conduction hearing aid into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective July 15, 2011. The classification was effective on March 31, 2011.

FOR FURTHER INFORMATION CONTACT: Vasant Dasika, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2443, Silver Spring MD 20993–0002, 301–796–5365.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on September 13, 2010, classifying the CLEAR 440 Series of hearing aids into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On October 13, 2010, Widex Hearing Aid Co. submitted a petition requesting classification of the CLEAR 440 Series of hearing aids under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and information submitted during interactive review, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name wireless air-conduction hearing aid, and it is identified as a wearable sound-amplifying device, intended to compensate for impaired hearing, that incorporates wireless technology in its programming or use.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

Identified risk	Required measures
Degradations in device function due to electromagnetic interference (EMI)	Electromagnetic compatibility (EMC) testing; labeling.
Degradations in device function due to wireless technology disruption such as slow-down, lost or corrupted information, security issues including potential cross-talk or control by other users with a similar medical device.	Wireless technology design, description, and testing; performance testing; labeling.
Exposure to non-ionizing radiation emitted by wireless technology can potentially induce tissue heating.	Wireless technology design, description, analysis, and testing; labeling.

FDA believes that the following special controls, in addition to general controls, address the risks to health and provide reasonable assurance of the safety and effectiveness of the device: (1) Appropriate analysis/testing should validate EMC and safety of exposure to non-ionizing radiation; (2) Design, description, and performance data

should validate wireless technology functions; and (3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation. Therefore, on March 31, 2011, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 874.3305.

Following the effective date of this final classification rule, any firm introducing a wireless air-conduction hearing aid into interstate commerce in the United States will need to comply with the special controls named in the regulation. However, the firm need only show that its device meets the recommendations of the special controls or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is exempt from premarket notification requirements.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from or in addition to'' certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); See *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. (See *Papike* v. *Tambrands, Inc.,* 107., 107 F.3d 737, 740–42 (9th Cir. 1997).)

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required.

VI. References

The following references have 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 Widex Hearing Aid Co., dated October 13, 2010.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section § 874.3305 is added to subpart D to read as follows:

§ 874.3305 Wireless Air-Conduction Hearing Aid.

(a) *Identification.* A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.

(b) *Classification:* Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electro magnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate wireless technology functions; and

(3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

(c) *Premarket notification.* The wireless air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

Dated: June 9, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–14790 Filed 6–14–11; 8:45 am]

BILLING CODE 4160–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Allocation of Assets in Single-Employer Plans; Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under the benefit payments regulation for valuation dates in July 2011 and interest assumptions under the asset allocation regulation for valuation dates in the third quarter of 2011. The interest assumptions are used for valuing and paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective July 1, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@PBGC.gov*), Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulations on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) and Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulations are also published on PBGC's Web site (*http://www.pbgc.gov*).

The interest assumptions in Appendix B to Part 4044 are used to value benefits for allocation purposes under ERISA section 4044. PBGC uses the interest assumptions in Appendix B to part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the asset allocation regulation are updated quarterly; assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for July 2011 and updates the asset allocation interest assumptions for the third quarter (July through September) of 2011.

The third quarter 2011 interest assumptions under the allocation regulation will be 4.21 percent for the first 25 years following the valuation date and 4.34 percent thereafter. In comparison with the interest assumptions in effect for the second quarter of 2011, these interest assumptions represent an increase of five years in the select period (the period during which the select rate (the initial rate) applies), an increase of 0.25 percent in the select rate, and an increase of 0.02 percent in the ultimate rate (the final rate).

The July 2011 interest assumptions under the benefit payments regulation will be 2.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for June 2011, these interest assumptions represent a decrease of 0.25 percent in the immediate annuity rate and are otherwise unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits under plans with valuation dates during July 2011, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 213, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
213	7–1–11	8–1–11	2.25	4.00	4.00	4.00	7	8