

TABLE 1—HIGH FLOW HUMIDIFIED OXYGEN DELIVERY DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, Non-clinical performance testing, and Labeling.
Interference with other devices	Electromagnetic compatibility testing, Radiofrequency identification testing, and Labeling.
Infection	Cleaning validation and Labeling.
Device software failure leading to delayed initiation of therapy	Software verification, validation, and hazard analysis; and Labeling.
Device failure/malfunction leading to ineffective treatment	Non-clinical performance testing and Labeling.
Electrical shock injury from device failure	Electrical safety, thermal safety, and mechanical safety testing.
Use error/improper device use leading to hypoxia or worsening hypercarbia.	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, high flow humidified oxygen delivery devices are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

We have 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control

number 0910–0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

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

■ 2. Add § 868.5454 to subpart F to read as follows:

§ 868.5454 High flow humidified oxygen delivery device.

(a) *Identification.* A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.

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

- (1) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:
 - (i) Alarm testing must be performed;

- (ii) Continuous use thermal stability testing must be performed;
- (iii) Humidity output testing must be performed; and
- (iv) Blender performance testing must evaluate fraction of inspired oxygen (FiO_2) blending accuracy.

(3) Performance data must validate cleaning instructions for any reusable components of the device.

(4) Electrical safety, thermal safety, mechanical safety, electromagnetic compatibility, and radiofrequency identification testing must be performed.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Labeling must include:

(i) A description of available FiO_2 ranges for different flowrates and inlet gas pressures;

(ii) Instructions for applicable flowrates for all intended populations;

(iii) A warning that patients on high flow oxygen are acute and require appropriate monitoring, to include pulse oximetry;

(iv) A warning regarding the risk of condensation at low set temperatures and certain flows; and

(v) A description of all alarms and their functions.

Dated: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2018–N–3772]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Active Implantable Bone Conduction Hearing System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the active implantable bone conduction hearing system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the active implantable bone conduction hearing system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 26, 2018. The classification was applicable on July 20, 2018.

FOR FURTHER INFORMATION CONTACT: Oldooz Hazrati, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2455, Silver Spring, MD 20993-0002, 240-402-9903, Oldooz.HazratiYadkooori@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the active implantable bone conduction hearing system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of

that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 16, 2017, MED-EL Elektromedizinische Geraete GmbH submitted a request for De Novo classification of the BONEBRIDGE. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 20, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.3340. We have named the generic type of device active implantable bone conduction hearing system, and it is identified as a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ACTIVE IMPLANTABLE BONE CONDUCTION HEARING SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Dural erosion or compression resulting from failure to confirm adequate thickness and consistency of bone and related anatomy.	Labeling.
Surgical complications leading to: <ul style="list-style-type: none"> • Bleeding/hematoma. • Seizures. • Cerebrospinal fluid (CSF) leak. • Implant damage or migration leading to revision/explantation 	Clinical performance testing and Labeling.
Device software failure	Software verification, validation, and hazard analysis.
Implant failure due to: <ul style="list-style-type: none"> • Fatigue. • Damage/breakage. • Loss of hermeticity 	Clinical performance testing and Non-clinical performance testing.
Device failure to compensate for hearing loss	Clinical performance testing and Non-clinical performance testing.
Interference with other devices	Electromagnetic compatibility testing, Wireless coexistence testing, Electrical safety testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation and Labeling.
Infection	Sterilization validation, Shelf life testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, active implantable bone conduction hearing systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

We have 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo

Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

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 part 874 is revised to read as follows:

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

- 2. Add § 874.3340 to subpart D to read as follows:

§ 874.3340 Active implantable bone conduction hearing system.

(a) *Identification.* An active implantable bone conduction hearing system is a prescription device consisting of an implanted transducer, implanted electronics components, and

an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone.

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

(1) Clinical performance testing must characterize any adverse events observed during implantation and clinical use, and must also demonstrate that the device performs as intended under anticipated conditions of use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Performance data must validate force output in a clinically relevant model.

(ii) Impact testing in a clinically relevant anatomic model must be performed.

(iii) Mechanical integrity testing must be performed.

(iv) Reliability testing consistent with expected device life must be performed.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(6) Performance data must demonstrate the wireless compatibility, electromagnetic compatibility, and electrical safety of the device.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Labeling must include:

(i) A summary of clinical testing conducted with the device that includes a summary of device-related complications and adverse events;

(ii) Instructions for use;

(iii) A surgical guide for implantation, which includes instructions for imaging to assess bone dimensions;

(iv) A shelf life, for device components provided sterile;

(v) A patient identification card; and

(vi) A patient user manual.

Dated: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 201

[Docket No. 2017-10]

Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: In this final rule, the Librarian of Congress adopts exemptions to the provision of the Digital Millennium Copyright Act (“DMCA”) that prohibits circumvention of technological measures that control access to copyrighted works, codified in the United States Code. As required under the statute, the Acting Register of Copyrights, following a public proceeding, submitted a Recommendation concerning proposed exemptions to the Librarian of Congress. After careful consideration, the Librarian adopts final regulations based upon the Acting Register’s Recommendation.

DATE: Effective October 28, 2018.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at regans@copyright.gov, Anna Chauvet, Assistant General Counsel, by email at achau@copyright.gov, or Kevin Amer, Senior Counsel for Policy and International Affairs, by email at kamer@copyright.gov. Each can be contacted by telephone by calling (202) 707-8350.

SUPPLEMENTARY INFORMATION: The Librarian of Congress, pursuant to

section 1201(a)(1) of title 17, United States Code, has determined in this seventh triennial rulemaking proceeding that the prohibition against circumvention of technological measures that effectively control access to copyrighted works shall not apply to persons who engage in noninfringing uses of certain classes of such works. This determination is based upon the Recommendation of the Acting Register of Copyrights, which was transmitted to the Librarian on October 5, 2018.¹

The below discussion summarizes the rulemaking proceeding and Register’s Recommendation, announces the Librarian’s determination, and publishes the regulatory text specifying the exempted classes of works. A more complete discussion of the rulemaking process, the evidentiary record, and the Acting Register’s analysis can be found in the Acting Register’s Recommendation, which is posted at www.copyright.gov/1201/2018/.

I. Background

A. Statutory Requirements

Congress enacted the DMCA in 1998 to implement certain provisions of the WIPO Copyright and WIPO Performances and Phonograms Treaties. Among other things, title I of the DMCA, which added a new chapter 12 to title 17 of the U.S. Code, prohibits circumvention of technological measures employed by or on behalf of copyright owners to protect access to their works. In enacting this aspect of the law, Congress observed that technological protection measures (“TPMs”) can “support new ways of disseminating copyrighted materials to users, and . . . safeguard the availability of legitimate uses of those materials by individuals.”²

Section 1201(a)(1) provides in pertinent part that “[n]o person shall circumvent a technological measure that effectively controls access to a work protected under [title 17].” Under the statute, to “circumvent a technological measure” means “to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner.”³ A

¹ Acting Register of Copyrights, Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Acting Register of Copyrights (Oct. 2018) (“Acting Register’s Recommendation”).

² Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4, 1998, at 7 (Comm. Print 1998).

³ 17 U.S.C. 1201(a)(3)(A).

technological measure that “effectively controls access to a work” is one that “in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copyright owner, to gain access to the work.”⁴

Section 1201(a)(1) also includes what Congress characterized as a “fail-safe” mechanism,⁵ which requires the Librarian of Congress, following a rulemaking proceeding, to publish any class of copyrighted works as to which the Librarian has determined that noninfringing uses by persons who are users of a copyrighted work are, or are likely to be, adversely affected by the prohibition against circumvention in the succeeding three-year period, thereby exempting that class from the prohibition for that period.⁶ The Librarian’s determination to grant an exemption is based upon the recommendation of the Register of Copyrights, who conducts the rulemaking proceeding.⁷ The Register, in turn, consults with the Assistant Secretary for Communications and Information of the Department of Commerce, who oversees the National Telecommunications and Information Administration (“NTIA”), in the course of formulating her recommendation.⁸

The primary responsibility of the Register and the Librarian in the rulemaking proceeding is to assess whether the implementation of access controls impairs the ability of individuals to make noninfringing uses of copyrighted works within the meaning of section 1201(a)(1). To do this, the Register develops a comprehensive administrative record using information submitted by interested members of the public, and makes recommendations to the Librarian concerning whether exemptions are warranted based on that record.

Under the statutory framework, the Librarian, and thus the Register, must consider “(i) the availability for use of copyrighted works; (ii) the availability for use of works for nonprofit archival, preservation, and educational purposes; (iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (iv) the effect of circumvention of technological measures on the market

⁴ *Id.* at 1201(a)(3)(B).

⁵ See H.R. Rep. No. 105-551, pt. 2, at 36 (1998) (“Commerce Comm. Report”).

⁶ See 17 U.S.C. 1201(a)(1).

⁷ *Id.* at 1201(a)(1)(C).

⁸ *Id.*