

Review Comment for Docket Number: 2005D-0344: Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tinnitus Masker Devices;

Neuromonics supports the issuance of a special controls guidance for tinnitus masker devices (TMDs) by the FDA. Neuromonics believes this document addresses the relevant issues associated with TMDs. There are however other issues that are also relevant to TMDs and it is important that these are included in the proposed special controls guidance document. With reference to the FDA's draft document, we include the following comments:

1) Identification of the risk analysis method (p.3 lines 36-40):

According to IEC 60601-1 *Medical Electrical Equipment, Part 1: General Requirements for Safety*, equipment shall cause no safety hazard in normal condition **and in single fault condition**.

Single fault conditions could occur for example upon failure of electrical insulation, contributing to one or more of the risks identified in the special controls guidance document **Section 6: Risks to Health**.

Therefore Neuromonics recommends that as a minimum the risk analysis method is used to assess risk while the device is in the normal condition **as well as** in single fault condition.

2) Grammatical omission (p. 5, line 22): "...the device is able to mask internal noises, it is also used an aid in hearing external...".

3) Electrical safety requirements (p. 7, lines 7 – 12)

Neuromonics recommends citing UL 60601-1 since it contains several important US national deviations to IEC 60601-1 (recommended in the draft special guidance); these include:

3.1) Flammability of Polymeric Enclosures and Covers

The U.S. national differences in UL 60601-1 require a minimum flame rating of UL 94V-2 for transportable equipment and UL 94V-0 for fixed or stationary equipment in accordance with "Standard for Polymeric Materials—Use in Electrical Equipment Evaluations," UL 746C.

3.2) Enclosure Mechanical Abuse Tests. Enclosure mechanical abuse tests (including the ball-impact test and drop test) are to be performed to ensure that the enclosure does not expose any live parts or cause a fire, electric shock, or mechanical hazard from these tests.

3.3) Leakage Current. The U.S. leakage current deviation is based on the values and requirements of NFPA 99, “Health Care Facilities” and the ANSI/AAMI “Safe Current Limits for Electromedical Apparatus” standards. The earth leakage current test per UL 60601-1 provides the worst-case conditions within the patient area, whereas the enclosure leakage current test per IEC 60601-1 is the worst-case test in the normal condition.

3.4) Components. According to UL, printed wiring boards, lithium batteries, optical isolators, wiring and tubing, CRTs that are greater than 5 in., and any component in the primary up to the safety isolation transformer need to meet nationally recognized standards (such as ANSI/UL standards) or internationally harmonized component standards.

3.5) Conductive Coatings. Conductive coatings such as used for electromagnetic compatibility (EMC) shielding need to be tested to confirm that the conductive coatings do not flake or peel, reducing spacings or bridging live parts, which could then cause a safety hazard.

3.6) Production-Line Tests. Production-line tests are required by UL per Annex DVB of UL 60601-1 which specifies the details for the dielectric voltage withstand, ground continuity, and single suspension system tests.

4) Preclinical Testing (p. 6, lines 20-23)

Neuromonics recommends that preclinical testing should include tests to verify that the sound output does not exceed applicable Occupational Health & Safety time-weighted exposure limits.

5) Clinical Studies (p. 7, lines 24-34)

Neuromonics recommends that no specific efficacy claims can be made without submitting supporting clinical data.

6) Professional Labeling (p. 8, lines 26 – 37)

Visible congenital or traumatic deformity of the ear is only a contraindication when it interferes with the efficacy of the tinnitus masking device. Therefore labeling should be more specific than providing a generic warning against visible congenital or traumatic deformities.

Labeling should also should recommend consulting with an Otolaryngology specialist in case of contraindications.

7) Patient labeling (p. 9, lines 15-20)

Neuromonics recommends that any patient labeling or user instructions warn users to discontinue use and seek medical evaluation if the patient experiences physical discomfort due either to auditory stimulation or mechanical interaction with the TMD.

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