(vi) Validation testing of device output and mechanical force applied to the tympanic membrane in a clinically appropriate model.

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

(4) Professional training must include the ear impression procedure, correct placement, fitting, monitoring, care, and maintenance of the device.

(5) Labeling must include the following:

(i) A detailed summary of the adverse events and effectiveness outcomes from the clinical performance testing;

(ii) Detailed instructions on how to fit the device to the patient;

(iii) Instructions for periodic cleaning of any reusable components;

(iv) Information related to electromagnetic compatibility; and

(v) Patient labeling that includes:

(A) A patient card that identifies if a patient has been fitted with any non-self- removable components of the device and provides relevant information in cases of emergency;

(B) Information on how to correctly use and maintain the device;

(C) The potential risks and benefits associated with the use of the device; and

(D) Alternative treatments.

[81 FR 3326, Jan. 21, 2015]

§ 874.3320 Group hearing aid or group auditory trainer.

(a) *Identification.* A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 84 FR 71813, Dec. 30, 2019]

§ 874.3325 Self-fitting air-conduction hearing aid.

(a) *Identification.* A self-fitting air-conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

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

(1) Clinical data must evaluate the effectiveness of the self-fitting strategy.

(2) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested.

(3) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.

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

(5) If the device incorporates wireless technology:

(i) Performance testing must validate safety of exposure to non-ionizing radiation;

(ii) Performance data must validate wireless technology functions; and

(iii) Labeling must specify instructions, warnings, and information relating to wireless technology and human exposure to non-ionizing radiation.

(6) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

(7) Patient labeling must include the following:

(i) Information on how a patient can self-identify as a candidate for the device;

(ii) Information about when to seek professional help;

(iii) A warning about using hearing protection in loud environments;