Guidance Document for Classification of Hearing Aids and Accessories

* according 93/42/EEC Medical Device Directive
* according to US CFR requirements

Blue color: Changes versus Revision 13

1. Introduction  
   The innovativeness of Hearing Aid industry is sometimes creating challenges in classifying Medical Devices and accessories according Annex IX of the 93/42/EEC Medical Device Directive and US CFR requirements.   
   This document serves as a guidance for Hearing Aid Industry to create a harmonized way within Industry to classify devices in the same manner.   
   A first issue was made within the prEN 50220 General requirements for hearing aids:

EUROPEAN HEARING INSTRUMENT MANUFACTURERS ASSOCIATION Annex Z 1 published in June 1998.

1. Scope  
   This document serves as a guidance document when classifying Hearing Aids and Accessories according to Medical Device Directive 93/42/EEC (MDD) and US CFR requirements.  
   Accessories falling under MDD definitions and US CFR definitions are covered.  
    For clarity some borderline examples of accessories not falling under the MDD are mentioned. They follow the definition of “Multipurpose products” acc to MEDDEV 2. 1/1 April 1994 1.1g  
   In addition “detachable parts” (See definition below) are mentioned as well for clarification.
2. References  
     
   EU  
   93/42/EEC Medical Device Directive Article 1 Definitions, scope   
   93/42/EEC Medical Device Annex IX Classification criteria  
   MEDDEV 2. 1/1 April 1994 Definition of "medical devices" , Definition of "accessory".....  
   MEDDEV 2. 4/1 Rev. 9 June 2010, Classification of medical devices  
   prEN 50220 General requirements for hearing aids: EUROPEAN HEARING INSTRUMENT MANUFACTURERS ASSOCIATION Annex Z 1 published in June 1998.   
   60601-2-66/FDIS MEDICAL ELECTRICAL EQUIPMENT – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems  
     
   US  
    SEC. 201. [21 U.S.C. 321] Definitions; generally  
   21CFR820 Sec. 820.3 Definitions SUBCHAPTER H--MEDICAL DEVICES   
   21CFR874. EAR, NOSE, AND THROAT DEVICES  
   Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Draft Guidance for Industry and Food and Drug Administration Staff

Document issued on: November 7, 2013  
Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff   
 Document issued on: September 25, 2013

1. Definitions   
   1. Definition according to chapter 201.1.1 Scope IEC 60601-2-66  
       ACCESSORY to HEARING INSTRUMENTS in HOME HEALTHCARE ENVIRONMENT (e.g. remote control units, audio streamers, battery chargers, power supplies) are covered by the most applicable standard, IEC 60065, IEC 60950-1 or other applicable IEC safety standards. Alternatively the general standard may be applied.   
      HEARING INSTRUMENTS do not have a MAINS PART intended for connection to a.c. SUPPLY MAINS. The connection to SUPPLY MAINS of a HEARING INSTRUMENT system is covered by power supply, charger or other types of ACCESSORIES.  
      NOTE Detachable parts of HEARING INSTRUMENTS even if supplied separately (e.g. ear hooks, domes, wax guards 205 ect.), are not regarded as ACCESSORY.
   2. SEC. 201. [21 U.S.C. 321] Definitions; generally  
      The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--  
      (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,  
      (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or..
   3. 21CFR820 Sec. 820.3 Definitions.   
      (l)Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized….
   4. Draft Guidance Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products  
      PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss…
   5. Mobile Medical Applications, Guidance for Industry  
      For purposes of this guidance, a “mobile medical app” is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)4; and either is intended:

• to be used as an accessory to a regulated medical device; or

• to transform a mobile platform into a regulated medical device….

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| 5. | Classification of Hearing Aids according to MDD 93/42/EEC | | | | | | |
| No. | Product | Classification according to 93/42/EEC Annex IX and MEDDEV 2.4/1 Rev 9 | Rule ac-cording to 93/42/EEC Annex IX | Accessory  According to MEDDEV 2.1/1 Apr 94 | Rationale for classification | Product to carry CE– mark acc to 93/42/EEC? Yes/No | Comment |
| 1.1 | Acoustical tubing  (for earmoulds, supplied with earmould) | Class IIa | Rule 9 | No |  | No | Tubing is a detachable part that may affect the acoustical properties of earmoulds, and hence the hearing aids. Tubing is part of a custom earmould, and has gone through conformity assessment of the hearing aid. |
| 1.2 | Acoustical tubing  (for earmoulds or domes, supplied separately) | Class I  (Chapter 3.2) | Rule 1 |  | MEDDEV 2.1/1 Apr 94 1.2 | Yes (if too small CE on accompanying document) | Tubing supplied separately can be classified and CE-marked separately after a separate conformity assessment if tubing can be used with “any” type of hearing aid. If shipped in bulk no CE-mark is needed. It is considered as a raw material. |
| 2. | ALD  (assistive listening device) | Depends on intended use |  | Yes/No | MEDDEV 2.1/1 Apr 94 1.2 | Yes | Examples are FM equipment, IR equipment, teleloop systems, radio, TV. Depending on the intended use, ALDs can be accessories to medical devices or not. |
| 3.1 | Audio Shoe (If supplied with hearing Aid) | Class IIa | 9 | Yes | MEDDEV 2.1/1 Apr 94 1.2 | No | Audio shoe specifically designed for a defined hearing aid model  Audio shoe is a detachable component that can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer. The audio shoe is not an integral part of the hearing aid. It is therefore defined as an accessory. It is specifically  intended by the manufacturer of the accessory to be used together with a Medical Device |
| 3.2 | Audio Shoe  (supplied separately) | Class I | 12 | Yes | MEDDEV 2.1/1 Apr 94 1.2 | Yes (if too small CE on accompanying document) | Audio shoe generically designed to work with many hearing aid models.  Audio shoe is a detachable component that can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer. The audio shoe is not an integral part of the hearing aid. It is therefore defined as an accessory. It is specifically  intended by the manufacturer of the accessory to be used together with a Medical Device |
| 4.1 | WL receiver e.g FM receiver designed for physical connection to Hearing Aid | I | 12 | Yes | MEDDEV 2.1/1 Apr 94 1.2 | Yes | FM link adapter does not convert signal and therefore is not an active medical device |
| 4.2 | WL FM receiver not in physical connection to Hearing Aid | I | 12 | Yes | MEDDEV 2.1/1 Apr 94 1.2 | Yes | FM link adapter converts signal and therefore is an active medical device |
| 5. | Battery  (primary cell) | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 6. | Battery (rechargeable) | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 7. | Battery tester | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 8. | Bone Conductor | IIa | Rule 9 |  | Active medical device  (non-invasive active therapeutic device that administers energy and acts by converting electrical output to vibration) | Yes | A bone conductor directly affects the output of hearing aids, and is therefore classified as IIa. They are also sold separate from the hearing aid, and must therefore be CE marked. |
| 9. | Behind-the-ear (BTE) hearing aids | IIa | Rule 9 |  | Active medical device (non-invasive active therapeutic device that administers energy in a non-potentially hazardous manner and acts by converting electrical output to acoustic output) | Yes | BTE hearing aids are classified as IIa |
| 10. | Body-worn hearing aids (BW) | IIa | Rule 9 |  | Active medical device (non-invasive active therapeutic device that administers energy in a non-potentially hazardous manner and acts by converting electrical output to acoustic output) | Yes | BW hearing aids are classified as IIa. |
| 11. | Charger  (for rechargeable batteries) | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 12 | Charger (designed for charging hearing aids including battery) | If MD then  I | If MD then  Rule I+12 |  | If MD then  MEDDEV 2.1/1 Apr 94 1.2 | Yes | Manufacturers can decide to classify as MD or not. If classified as MD following rationale should be used.  Battery chargers specifically intended for recharging hearing aid batteries are non-invasive and are active devices because they act by converting energy. |
| 13.1 | Cleaning fluid (not disinfecting, to clean hearing aids/earmoulds by the user) | I | Rule I |  | Non-invasive. Rules 2,3,4 does not apply. | Yes | Cleaning fluid is a medical device, but only if specifically developed to clean hearing aids etc. |
| 13.2 | Cleaning fluids (that have disinfecting function to disinfect hearing aids/earmoulds by the user) | IIb | Rule 15 |  | MEDDEV 2.4/1 June 2012 Rev 9 | Yes | Specific cleaning fluids for disinfection |
| 14. | Cord  (includes cord between receiver and Bodyworn) | - |  |  |  | No | If the cord can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer, the cord is not an integral part of the hearing aid. It is therefore defined as an accessory, but is - since it may be used for other purposes - not a medical device. |
| 15. | CROS unit  (including microphone and potentially a telecoil) | I | Rule 12 | Yes | MEDDEV 2.1/1 Apr 94 1.2 | Yes (if too small CE on accompanying document) | An option, a detachable part and hence not an integral part of the hearing aid |
| 16. | Dummy hearing aid | - |  |  |  | No | Not functional, and therefore not a medical device |
| 17.1 | Earmould (custom-made) | IIa | Rule 5 |  | Earmoulds are invasive device connected to an active device | No | An earmould is a detachable part that can affect safety. Custom-made earmoulds cannot be CE-marked, but must comply with the MDD, Annex VIII- |
| 17.2 | Earmould | IIa | Rule 5 | 1.1c | Earmoulds are invasive device connected to an active device | Yes | An earmould is a detachable part that can affect safety. Goes with Annex II. Article 1 Part d. If size is too small CE to put on accompanying doc:s |
| 18. | Ear dome (standard e.g dome) | IIa | Rule 5 |  | Earmoulds are invasive devices connected to an active device | Yes | An earmould is a detachable part that can affect safety |
| 19. | Earphone  (e,g used with bodyworn) | IIa | Rule 9 |  | Earphone is an active device | Yes | An earphone directly affects the output of body worn hearing aids, and is therefore classified as IIa. It is also sold separate from the hearing aid, and must therefore be CE-marked |
| 20. | Eyeglass hearing aid (EG) | IIa | Rule 9 |  | EG is an active device | Yes | Eyeglass hearing aids are classified as IIa |
| 21. | Eyeglass adaptor | IIa | Rule 9 |  |  | No | An option, and hence an integral part of the hearing aid |
| 22. | Ear Hook | IIa | Rule 9 |  |  | No | A detachable part, and hence an integral part of the hearing aid |
| 23. | Impression material | I | Rule 5 |  | Impression material is invasive material in transient use | Yes | A substance that, although for temporary use, may have health and safety implications. Hence classified as I |
| 24. | In-the-ear (ITE) / custom made hearing aid | IIa | Rule 5 |  | ITE/custom made hearing aids are invasive devices | Yes | ITE /custom made hearing aids are classified as IIa. Faceplates should be CE-marked. This refers to Article 1 (d) definitions of custom made devices second section stating “Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user are not considered to be custom-made devices” |
| 25. | ITE assembly In-the-ear (ITE) / custom made hearing aid | Custom |  | 1.1c |  | No | If an operator assembles ITEs deviating from an approved manufacturer’s instructions, such aids are classified as custom devices, cannot be CE-marked, but must comply with MDD, Annex VIII  This is an alternative way to classify custom products and refers to Article 1 (d) definitions of custom made devices first section stating “'custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.” |
| 26. | ITE kit | IIa |  |  |  | Yes | ITE hearing aids are classified as IIa. They may be ear-marked, provided the assembler adheres to the manufacturer’s instructions |
| 27. | Maintenance tool   (e.g brush tool, wax guard tool etc) | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 28. | PC (for programming) | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Multipurpose product and though not an accessory according to MDD |
| 29.1 | Programming interface (e.g Hi Pro, NOAH link) | IIa | Rule 5 | Yes | MEDDEV 2.1/1 Apr 94 1.1f,1.2 | Yes | A programming device intended to be temporarily (transient) connected by wire to a Hearing aid transmitting predefined program into the hearing aid. For an In –The –Ear hearing aid the programming cable extends into the ear canal making it invasive. Therefore Rule 5 applies.  Rule 9 does not apply due to lack of therapeutic functionality. |
| 29.2 | Programming Interface  (Wireless) | I | Rule 12 | Yes | MEDDEV 2.1/1 Apr 94 1.2 |  | A wireless programming device specifically intended to be used with Hearing Aid transmitting a program wirelessly by a signal (energy), between a PC or similar device that alters/manages the program to a he-aring aid (active medical device class IIa) without any significant change. |
| 30. | Remote control (integral) | IIa | Rule 9 |  | Active device | Yes | An integral remote control is an essential part of the hearing aid, since the aid will not function without. Nevertheless it may be sold separately, and must therefore be independently CE-marked |
| 31. | Remote control (optional) | I | Rule 12 |  |  | Yes | An optional remote control is an accessory that is sold separately, but is intended to control the hearing aid parameters in use. It is therefore classified as I |
| 32.1 | Remote microphone | I | Rule 12 |  | MEDDEV 2.1/1 Apr 94 1.2 | Yes | A dedicated microphone specifically designed and intended to be used with hearing aids. |
| 32.2 | Remote microphone | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No/Yes | Multipurpose product occasionally used in the medical environment and not specifically designed to be used with hearing aids |
| 33. | Repair tool | No | No | No | MEDDEV 2.1/1 Apr 94 1.1g | No | Repair tools are Multipurpose product and though not an accessory according to MDD. |
| 34. | Software (fitting) | IIa | Rule 9 |  | MEDDEV 2.4/1 chapter 3.1.4 | Yes | PC-based software for hearing aid fitting |
| 35. | Software (integrated) | IIa | Rule 9 |  | MEDDEV 2.4/1 chapter 3.1.4 | No | An integral part of the hearing aid |
| 36. | Spare part | No | No |  | Ref MEDDEV 2.1/1 Apr 94 1.1b | No | Spare parts for service/repair are not medical devices |
| 37. | Tamperproof battery cover | IIa |  |  |  | No | An option, and hence an integral part of the hearing aid |
| 38. | Volume control cover | IIa |  |  |  | No | An option, and hence an integral part of the hearing aid |
| 39. | Wax filter | IIa |  |  |  | No | An option, and hence an integral part of the hearing aid. To be seen as a spare part. |
| 40. | Receiver in the Ear unit | IIa | Rule 9 | No |  | No | A detachable part that is an integral part of the hearing aid |
| 41. | APP  (That does not drive or influence the device) | I | Rule 12 | Yes | Annex IX  sec. 1.4 | Yes | An APP that has an intended purpose covered by MDD and has no diagnostic purpose and doesn’t include a Remote Control function of the hearing aid. |
| 42. | APP (that drives or influences the device) | IIa | Rule 9 | Yes | Annex IX, 3.2 | Yes | This could be an APP including a Remote Control that changes a program setting or directly influences the SW parameters of the device |
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| 6. |  | Classification of Hearing Aids according to FDA regulations | | | | | | |
| No. | Product | | Classification according to FDA regulation | Regulation | Definition documented in FDA regulations | Product Code acc to FDA | Pre market approval | Comment |
| 1.1 | Acoustical tubing  (for earmoulds, supplied with earmould) | | Classification  follows the device | Regulation follows device |  |  | Depends on the hearing aid. | Tubing is a detachable part that may affect the acoustical properties of earmoulds, and hence the hearing aids. Tubing is part of a custom earmould, and has gone through conformity assessment of the hearing aid. |
| 1.2 | Acoustical tubing  (for earmoulds or domes, supplied separately) | | Classification  follows the device | Regulation follows device |  |  | Depends on the hearing aid | Tubing supplied separately can be classified separately if tubing can be used with “any” type of hearing aid. |
| 2. | ALD  (assistive listening device  excluding  Group hearing aid or group auditory trainer.) | | Not a medical device | N/A (PSAP regulations ?) |  |  |  | Examples are FM equipment, IR equipment, teleloop systems, radio, TV. Depending on the intended use, ALDs can be accessories to medical devices or not. |
| 2.1 | ALD  (assistive listening device Group hearing aid or group auditory trainer.) | | Class 2 | 874.3320 | 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. | EPF | 510k required |  |
| 3.1 | Audio Shoe (If supplied with hearing Aid) | | Classification  follows the device | Regulation follows device |  |  |  | Audio shoe specifically designed for a defined hearing aid model  Audio shoe is a detachable part that can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer. The audio shoe is not an integral part of the hearing aid. It is therefore defined as an accessory. It is specifically intended by the manufacturer of the accessory to be used together with a Medical Device |
| 3.2 | Audio Shoe  (supplied separately) | | Classification  follows the device | Regulation follows device |  |  |  | Audio shoe generically designed to work with many hearing aid models.  Audio shoe is a detachable component that can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer. The audio shoe is not an integral part of the hearing aid. It is therefore defined as an accessory. It is specifically  intended by the manufacturer of the accessory to be used together with a Medical Device |
| 4.1 | WL receiver e.g FM receiver designed for physical connection to Hearing Aid | | Classification  follows the device | Regulation follows device |  |  |  | FM link adapter converts signal and therefore is an active medical device |
| 4.2 | WL FM receiver not in physical connection to Hearing Aid | | Classification  follows the device | Regulation follows device |  |  |  | FM link adapter converts signal and therefore is an active medical device |
| 5. | Battery  (primary cell) | | No | No |  |  |  | Multipurpose product and though not an accessory according to MDD |
| 6. | Battery (rechargeable) | | No | No |  |  |  | Multipurpose product and though not an accessory according to MDD |
| 7. | Battery tester | | No | No |  |  |  | Multipurpose product and though not an accessory according to MDD |
| 8. | Bone Conductor (no implant) | | Class 2 | 874.3300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400) | LXB | not exempted from 510k | A bone conductor directly affects the output of hearing aids.. |
| 9. | Behind-the-ear (BTE) hearing aids | | Class 1 | 874.3300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400) | ESD | Exempted from 510k | (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 9.1 | Wireless Behind-the-ear (BTE) hearing aids | | Class 2 | 874.3305 | wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use. | OSM | Exempted from 510k | (special controls). The special controls for this device are (see 874.3305) |
| 10. | Body-worn hearing aids (BW) | | Class 1 | 874.3300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400) | ESD | Exempted from 510k | (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 11. | Charger  (for rechargeable batteries) | | No | No |  |  |  | Multipurpose product and though not an accessory |
| 12 | Charger (designed for charging hearing aids including battery) | | No | No |  |  |  | Manufacturers can decide to classify as MD or not. If classified as MD following rationale should be used. If battery cannot be removed from hearing aid it is an accessory to a hearing aid |
| 13.1 | Cleaning fluid (not disinfecting, to clean hearing aids/earmoulds by the user) | | No | No |  |  |  | Cleaning fluid is a medical device, but only if specifically developed to clean hearing aids etc. |
| 13.2 | Cleaning fluids (that have disinfecting function to disinfect hearing aids/earmoulds by the user) | | Class I (general controls). | 880.6890 General purpose disinfectant | . A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin. | LRJ | exempt | Specific cleaning fluids for disinfection exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9. |
| 14. | Cord  (includes cord between receiver and Bodyworn) | | No | No |  |  |  | If the cord can be removed from the hearing aid, and the hearing aid still works as intended by the manufacturer, the cord is not an integral part of the hearing aid. It is therefore defined as an accessory, but is - since it may be used for other purposes - not a medical device. |
| 15. | CROS unit  (including microphone and potentially a telecoil) | | Classification  follows the device | Regulation follows device |  |  |  | An option, and hence not an integral part of the hearing aid. Though an accessory |
| 16. | Dummy hearing aid | | No | No |  |  |  | Not functional, and therefore not a medical device |
| 17.1 | Earmould (custom-made) | | Classification  follows the device | Regulation follows device |  |  |  | An earmould is a detachable part that can affect safety. |
| 17.2 | Ear mold | | Classification  follows the device | Regulation follows device |  |  |  | An earmould is a detachable part that can affect safety. |
| 18. | Ear dome (standard e.g dome) | | Classification  follows the device | Regulation follows device |  |  |  | An earmould is a detachable part that can affect safety |
| 19. | Earphone  (e,g used with bodyworn) | | Classification  follows the device | Regulation follows device |  |  |  | An earphone directly affects the output of body worn hearing aids. |
| 20. | Eyeglass hearing aid (EG) | | Class I | 874.300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400) | ESD | Exempted from 510k | (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 21. | Eyeglass adaptor | | Classification  follows the device | Regulation follows device |  |  |  | An option, and hence an integral part of the hearing aid |
| 22. | Ear Hook | | Classification  follows the device | Regulation follows device |  |  |  | A detachable part, and hence an integral part of the hearing aid |
| 23. | Impression material | | N/A | Not classified | Defined under “Kit, earmold , impression” in FDA data base | LDG | 510(k) pre-amendment | A substance that, although for temporary use, may have health and safety implications.  (Unclear if this relates to implanted middle ear mold or to ear molds used for air conduction hearing aids. ) |
| 24. | In-the-ear (ITE) / custom made hearing aid | | Class 1 | 874.300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400 | ESD  (LRB=  Face plate) | Exempted from 510k | Faceplates have their own product code = LRB and are considered as a component.  (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 24.1 | Wireless In-the-ear (ITE) / custom made hearing aid | | Class 2 | 874.3305 | wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use. | OSM  (LRB=  Face plate) | Exempted from 510k  (special controls). The special controls for this device are (see 874.3305) | Faceplates have their own product code = LRB and are considered as a component. |
| 25. | ITE assembly In-the-ear (ITE) / custom made hearing aid (Non WL) | | Class 1 | 874.300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400 | ESD  (LRB=  Face plate) | Exempted from 510k | Faceplates have their own product code = LRB and are considered as a component.  (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 26. | ITE kit  (Non WL) | | Class 1 | 874.300 | A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400 | ESD  (LRB=  Face plate) | Exempted from 510k | Faceplates have their own product code = LRB and are considered as a component.  (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9. |
| 27. | Maintenance tool   (e.g brush tool, wax guard tool etc) | | No | No |  |  |  | Multipurpose product and though not an accessory |
| 28. | PC (for programming) | | No | No |  |  |  | Multipurpose product and though not an accessory |
| 29.1 | Programming interface (e.g Hi Pro, NOAH link) | | Classification  follows the device | Regulation follows device |  |  |  | A programming device intended to be temporarily (transient) connected by wire to a Hearing aid transmitting predefined program into the hearing aid. For an In –The –Ear hearing aid the programming cable extends into the ear canal making it invasive. |
| 29.2 | Programming Interface  (Wireless) | | Classification  follows the device | Regulation follows device |  |  |  | A wireless programming device specifically intended to be used with Hearing Aid transmitting a program wirelessly by a signal (energy), between a PC or similar device that alters/manages the program to a hearing aid without any significant change. |
| 30. | Remote control (integral) | | Classification  follows the device | Regulation follows device |  |  |  | An integral remote control is an essential part of the hearing aid, since the aid will not function without. |
| 31. | Remote control (optional) | | Classification  follows the device | Regulation follows device |  |  |  | An optional remote control is an accessory that is sold separately, but is intended to control the hearing aid parameters in use. |
| 32.1 | Remote microphone | | Classification  follows the device | Regulation follows device |  |  |  | A dedicated microphone specifically designed and intended to be used with hearing aids. |
| 32.2 | Remote microphone | | No | No |  |  |  | Multipurpose product occasionally used in the medical environment and not specifically designed to be used with hearing aids |
| 33. | Repair tool | | No | No |  |  | No | Repair tools are Multipurpose product and though not an accessory according to MDD. |
| 34. | Software (fitting) | | Classification  follows the device | Regulation follows device |  |  |  | PC-based software for hearing aid fitting |
| 35. | Software (integrated) | | Classification  follows the device | Regulation follows device |  |  |  | An integral part of the hearing aid |
| 36. | Spare part | | No | No |  |  |  | Spare parts for service/repair are not medical devices |
| 37. | Tamperproof battery cover | | Classification  follows the device | Regulation follows device |  |  |  | An option, and hence an integral part of the hearing aid |
| 38. | Volume control cover | | Classification  follows the device | Regulation follows device |  |  |  | An option, and hence an integral part of the hearing aid |
| 39. | Wax filter | | No | No |  |  |  | An option, and hence an integral part of the hearing aid. To be seen as a spare part. |
| 40. | Receiver in the Ear unit | | Classification  follows the device | Regulation follows device |  |  |  | A detachable part that is an integral part of the hearing aid |
| 41 | Tinnitus masker | | Class 2 | 874.3400 | A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in | KLW | (special controls). The special controls for this device are (see 874.3400)  510 k required |  |
| 41. | APP  (That does not drive or influence the device) | | Classification  follows the device | Regulation follows device | * Mobile Medical Application (Mobile Medical App)   + a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)4; and either is intended:   to be used as an accessory to a regulated medical device; |  |  | * An APP that might have diagnostic purpose and doesn’t include a RC or has a function that directly influences the device. |
| 42. | APP (that drives or influences the device) | | Classification  follows the device | Regulation follows device | * Mobile Medical Application (Mobile Medical App)   + a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)4; and either is intended:   •to be used as an accessory to a regulated medical device; or  • to transform a mobile platform into a regulated medical device |  |  | An APP including a Remote Control that changes a program setting or directly influences the SW parameters of the device |
|  |  | |  |  |  |  |  |  |