Classification of Tactile Hearing Aids under Product Code “LRA”

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Tactile Hearing Aids

- Intended to convert sound to tactile sensation for speech training and interpreting sounds from other people and the environment
- Regulated under product code “LRA” as “Hearing Aid, Tactile”
- There have been 8 clearances for tactile hearing aids via the 510(k) process (1981-1988)
Device Descriptions

• Most of the tactile hearing aids are portable, battery-powered, body-worn, and skin-contacting devices. They utilize a “sensory substitution” principle to provide awareness of sound through tactile sensation.

• The term “vibrotactile aid” is used synonymously with “tactile hearing aid” since the majority of these devices use a vibratory sensation on the skin to represent acoustic sounds.
Device Descriptions (cont’d)

- Examples of how these devices function are provided below:
  
  » Vibratory sensation is induced by electromechanical forces and delivered to the skin via a vibratory stimulator held in place by a strap. Sound is first converted to electrical impulses which are then transmitted to the user via mechanical vibrations.

  » Some do not convert it to mechanical vibrations, but instead utilize electrodes that deliver low-level current to the skin to elicit a tactile sensation that represents acoustic sounds.
Indications for Use

• The device is a wearable tactile system for the deaf and deaf-blind. It is an important aid for speech training and acousto-vibratory communication.

• The device is a vibrotactile aid to assist hearing-impaired patients in sound recognition. It uses a sensory substitution principle and has been designed for preschool and school-age children with severe to profound hearing loss. It translates sound into tactile stimuli and thus is an adjunct device to auditory perception and/or lipreading training.
Indications for Use (cont’d)

• The device is an electrotactile aid to hearing primarily for the profoundly deaf. The device operates by detecting sound and then processing it to an output which can be interpreted by the user via the sense of touch. It is a multichannel device, and it can be useful, with practice, in aiding the hearing impaired individual in the interpretation of the spoken word and environmental sounds.
Adverse Events and Risks

• Manufacturer and User facility Device Experience (MAUDE) database (1992-2015)
• Information available to FDA regarding cleared devices
• Review of literature on PubMed (up to 2015):
  » (“tactile hearing aid” OR “vibrotactile hearing aid”)
  » (“tactile hearing aid” OR “vibrotactile hearing aid” AND “adverse event”)
  » (“tactile hearing aid” OR “vibrotactile hearing aid” AND “complication”)

Adverse Events and Risks

• No Medical Device Reports (MDRs) were found
• No adverse events or complications were noted in the literature search
• However, devices have not been widely used
• Experience with the long-term effects of chronic, direct vibratory stimulation on the skin is limited
• Some devices utilize cutaneous electrical stimulation which introduces the risk of tissue damage
Risks

• Adverse tissue reaction to device including foreign body reaction, inflammation and granuloma formation

• Local burns and/or tissue damage or overstimulation due to inappropriate stimulation parameters, electromechanical interference, heat, and/or mechanical forces

• Local tissue injury due to material alteration or breakage

• Local tissue injury or overstimulation due to incorrect placement or use of device
## Risks and Mitigations

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<tr>
<th>Identified Risk</th>
<th>Recommended Mitigation Measure</th>
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| Adverse tissue reaction to device including foreign body reaction, inflammation and granuloma formation | • Biocompatibility testing  
• Labeling                                                                                       |
| Local burns and/or tissue damage or overstimulation due to inappropriate stimulation parameters, electromechanical interference, heat, and/or mechanical forces | • Performance Testing – Bench (electrical, thermal, mechanical, and software safety, as well as electro-magnetic compatibility)  
• Labeling                                                                                       |
| Local tissue injury due to material alteration or breakage                      | • Performance Testing – Bench (mechanical)  
• Labeling                                                                                       |
| Local tissue injury or overstimulation due to incorrect placement or use of device | • Labeling                                                                                       |
Proposed Classification Regulation

874.XXXX Tactile Hearing Aid

(a) Identification. A tactile hearing aid is a device that converts sound to tactile sensation, stimulating the skin surface to aid in speech training and interpreting sounds from other people and the environment. This generic type of device uses either vibrotactile stimulation by electromechanical forces delivered to the skin via a vibratory stimulator, or uses electrical stimulation of the skin via electrode array(s) to represent acoustic sound.
874.XXXX Tactile Hearing Aid

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

(1) The labeling must include adequate warnings/precautions and instructions regarding the proper placement and use of the device.
(2) The device must be demonstrated to be biocompatible.
(3) Performance testing must demonstrate electrical, thermal, mechanical, and software safety, as well as electromagnetic compatibility consistent with the mechanism by which they provide stimulation. Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use. Electrical and software testing must demonstrate the proper limiting of the maximum output of the device and safety of stimulation parameters.
Questions to Panel for Product Code “LRA”
Question 1 to Panel

Please comment on whether you agree with inclusion of all of these risks in the overall risk assessment of the tactile hearing aids under product code “LRA.” In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of the tactile hearing aids under product code “LRA.”
Question 2 to Panel

Please discuss whether the following special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

- The labeling must include adequate warnings/precautions and instructions regarding the proper placement and use of the device.
- The device must be demonstrated to be biocompatible.
- Performance testing must demonstrate electrical, thermal, mechanical, and software safety, as well as electromagnetic compatibility consistent with the mechanism by which they provide stimulation. Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use. Electrical and software testing must demonstrate the proper limiting of the maximum output of the device and safety of stimulation parameters.
FDA proposes that tactile hearing aids be regulated as Class II devices (special controls.)

Please discuss whether you agree with FDA’s proposed classification of Class II for these devices. If you do not agree with FDA’s proposed classification, please provide your rationale for recommending a different classification.
End of Panel Questions for Product Code “LRA”