



This letter is done on behalf of Intricon Corporation (subsequently referred to as “Intricon”), the manufacturer of the hardware and firmware of the Lumen 155 hearing aids to declare that the Intrisound Tuned Lumen 155 self-fitting wireless air conduction over-the-counter hearing aid (K223848) is identical to the JVC EH-Z1500 device in all aspects except the name itself.

The Lumen 155 hearing aid has been on the market since 2018 under product code OSM, Prescription Air-Conduction with Wireless Technology Hearing Aid, class 2/Exempt, regulation 874.3305. The Lumen 155 is coupled with the Tuned self-fitting application software to create an over-the-counter self-fitting air conduction hearing aid (Intrisound Tuned Lumen 155) in accordance with 21 CFR 800.30 under product code QUH. The Intrisound Tuned Lumen 155 device is referred to in various documents as Lumen 155, Lumen 155i, Lumen 155-SF, Felix 8750, Lumen hearing aid, JVC EH-Z1500 or similar names, all of which refer to the same hearing aid physical embodiment with no changes to the final finished form of the device.

All biocompatibility testing from the Lumen 155 base platform applies equally to the JVC EH-Z1500 since they are the exact same hearing aid in its final finished form. Other collateral test and regulatory requirements such as those defined by the Restriction of Hazardous Substances (RoHS) and the Federal Communications Commission (FCC) are also identical from the Lumen 155 base platform to the JVC EH-Z1500 device in its final finished form. The JVC EH-Z1500 device uses the same self-fitting algorithm as the Intrisound Tuned Lumen 155 which was FDA 510(k) cleared under K223848.

All polymers, resins, coatings, composites, and all other physical characteristics and attributes of the JVC EH-Z1500 hearing aid in its final finished form are identical to all polymers, resins, coatings, composites, and all other physical characteristics and attributes of the Lumen 155 (legally US-marketed) device in formulation, processing, sterilization, and geometry. No other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). The JVC EH-Z1500 has no changes in chemical composition of the raw material, material processing, manufacturing, or residual manufacturing aids that may be present on the device in its final finished form compared to those of the Lumen 155. The physical aspects of both hearing aids are identical (e.g., Lumen 155 in any named variants and the JVC EH-Z1500 device).

Best regards,

David Akbari, Au.D.

Senior Medical Science, Clinical and Regulatory Affairs Liaison

Intricon Corporation

