

**Audallion® II Hearing System**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Substantial equivalence for the Audallion® II Hearing System to the predicate device, the ReSound® BT4 Personal Hearing System™, 510(k) No. K964557, Nov. 27, 1996, is based on the following:

- This air-conduction behind-the-ear hearing instrument with body-worn processor is intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for hearing losses from mild to severe.
- The device is powered by a standard hearing aid battery (type 13) and 2 standard alkaline type AAA batteries.
- The device is manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices.
- The intended use, performance specifications, functions and operations of the Audallion® II Hearing System are essentially identical to that described in the 510(k) Premarket Notification for the ReSound® BT4 Personal Hearing System™.
- The ability to program digitally the fitting parameters of the hearing device is the same as in the ReSound® BT4 Personal Hearing System™, as is the ability to change the characteristics of the sound processing and adjust the volume.
- The Audallion® II Hearing System has the ability to retain up to four programs in memory, whereas the predicate device has the ability to retain two.