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**ReSound® Personal Hearing Systems EDR Encore Series**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

Substantial equivalence for the ReSound® Personal Hearing Systems EDR Encore Series: Models EDR-E, EDR-ES, EDR-EV, and EDR-P1 to the predicate device, the ReSound® Personal Hearing System ED3-E, 510(k) No. K950319, February 8, 1995, is based on the following:

- These air-conduction hearing instruments are 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 moderately-severe.
- These devices are powered by a standard hearing aid battery (type 13).
- These devices are 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 ReSound® Personal Hearing Systems EDR Encore Series are substantially equivalent to that described in the 510(k) Premarket Notification for the ReSound® Personal Hearing System ED3-E.
- The ability to program digitally the fitting parameters of the hearing devices and the ability of the devices to retain one program, even when the main battery is removed and changed, is the same as in the ReSound® Personal Hearing System ED3-E. The EDR-E, EDR-ES, and EDR-EV are dispenser programmable, whereas the EDR-P1 programming is factory preset and may be reprogrammed at the factory only.