

ReSound® CC4 Personal Hearing System™

SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial equivalence of the ReSound® CC4 Personal Hearing System™ to the ReSound® Personal Hearing System™ ED4-C (now known as the IC4), 510(k) No. K951067, May 12, 1995, is based on the following:

- This air-conduction hearing instrument 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 moderate.
- The device is powered by a standard hearing aid battery (type 10A).
- 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 ability of the hearing aid dispenser to program digitally the fitting parameters of the ReSound® CC4 hearing device is the same as in the ReSound® IC4.
- The ability to change the characteristics of the sound processing and to adjust the volume via an optional remote control is the same as that offered by the commercial device, the ReSound® IC4.
- The algorithm used by the ReSound® computerized fitting system to compute sets of fitting parameters is similar to that used for the ReSound® IC4 with adjustments made for the acoustic differences between the IC4 and the ReSound® CC4.
- The performance specifications, functions and operations of the ReSound® CC4 Personal Hearing System™ is substantially equivalent to that described in the predicate device 510(k) Premarket Notification.