

K953872

APR 12 1996

**Section 510(k)
Premarket Notification
Summary of Safety and Effectiveness Information**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Trade Name: Second Ear® Bone Conduction Hearing Aid

2. Common / Classification Name:

Common Name: Bone Conduction Hearing Aid

Classification Name: Hearing Aid

3. Applicant / Sponsor Name / Address:

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4. Contact Person:

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5. Establishment Registration Number:

Number: 9021402

6. Classification:

§ 874.3300 Hearing Aid. (a) Identification. A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400). (b) Classification. (1) Class I for the air-conduction hearing aid. (2) Class II for the bone-conduction hearing aid.

Device Class: Class II

Classification Panel: Ear, Nose & Throat Devices Panel

Classification Code: 77LXB

7. Substantially Equivalent Device(s):

1. Starkey Model BC1 Bone Conduction CROS Hearing Aid
2. Unitron[®] Bone Conduction Hearing Aid
3. Radioear B70 Series Audio Transducers

8. Device Description:

The EC-1000 *Second Ear*[®] is a bone conduction-type hearing aid. Unlike conventional products which depend upon acoustic coupling through air, the EC-1000 *Second Ear*[®] is based on bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the outer and middle ear.

The EC-1000 *Second Ear*[®] offers an innovative tone control system, providing flexible audio control adjustments. Also, features such as a voice filter which when selected, reduces additional exterior sound. As an added feature an auxiliary input jack allows the user to connect *Second Ear*[®] directly to TV, CD players, portable radios, tape players or even telephones.

State of the art nickel-metal-hydride rechargeable battery technology is used for maximum battery life while minimizing size and weight.

Transducer

The EC-1000 *Second Ear*[®] consists of a transducer unit, a shirt pocket sized audio processor/driver module and a wire cable for connecting the transducer with the audio processor/driver. The transducer is a convenient sized unit that is held against the head and is driven electrically to transmit audio vibrations to the underlying bones of the skull. It is a low-impedance device, similar to a loudspeaker.

Audio Processor/Driver

The audio processor/driver module connects the transducer through the wire cable and usually would be carried in the users pocket. The wire cable connecting the audio processor/driver and the transducer can be placed comfortably at sensitive bone-conductive location such as behind-ear.

The audio processor/driver module is completely self-contained and is battery powered. It also has a built-in microphone for picking up sound. A rechargeable battery pack is the power source.

Battery Pack

The battery pack can be charged in place in the unit or snapped out for easy exchanging. By purchasing a spare battery pack, the user can be using one battery while charging the other, guaranteeing uninterrupted use of the EC-1000. The user should be able to obtain 24 to 48 hours of operation in normal use from fully charged batteries. Volume setting and environmental conditions affect battery life.

Packaging:

Standard packaging is used in the production of this device. Packaging quality is sufficient to protect the device from damage during transportation and storage. When not in use, the device should be stored in the same package as when it was supplied.

Equivalence:

The *Second Ear*[®] Bone Conduction Hearing Aid is equivalent to the Starkey Labs, the Unitron brand bone conduction hearing aids and the Radioear Audio Transducer. The referenced units provide amplified auditory information via bone conduction as does the *Second Ear*[®]. All units are intended for use by persons with moderate to severe conductive hearing losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.

The frequency response of the *Second Ear*[®] Bone Conduction Hearing Aid without the voice filter is 150 Hz to 8 KHz. When the voice filter is engaged, response is 300 Hz to 3 KHz. The frequency response of the Unitron[®] brand bone conduction hearing aids is between 100 Hz and 6.6 KHz depending upon the unit selected. The *Second Ear*[®] is also equipped with treble and bass controls.

Power requirements for the *Second Ear*[®] Bone Conduction Hearing Aid are supplied by a Nickel-Metal-Hydride battery. The *Second Ear*[®] Bone Conduction Hearing Aid is provided with a 12 V, 750mA AC adapter and battery charger while the competitive brands typically utilize disposable batteries. Fully charged battery capacity is 600mA-hrs for the *Second Ear*[®] and is approximately the same for the competitive bone conduction hearing aids.

The sound conduction transducers of the *Second Ear*[®] and the comparison units are placed against the users skin behind the ear or other bony location of the skull with the aid of a strap or headband. Maximum voltage gain for the *Second Ear*[®] Bone Conduction Hearing Aid is 57dB. Overall S/N ratio for the *Second Ear*[®] is 40dB.

Conclusion:

A review of the provided performance specifications for the *Second Ear*[®] and the listed comparison devices shows that all three devices are substantially the same in terms of indications for use, function, form, design, materials and performance. The feature comparison table below summarizes this information.

FEATURE COMPARISON TABLE

| FEATURE | Second Ear [®] | Unitron | Radioear | Starkey Labs. | S. E.? |
|-----------------------------|---|--|---|--------------------|--------|
| Materials: | Medical grade plastic | Same | Same | Same | Yes |
| Indications for Use: | Moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms | Same | Same | Same | Yes |
| Power Requirement: | 4.8 VDC Nickel-Metal-Hydride Battery | R675 & R6-AA Nickel Metal & Alkaline Battery | NiCad, R675 & R6-AA Nickel Metal & Alkaline Battery | NiCad. | Yes |
| Frequency Response | 150Hz to 8 KHz 300Hz to 3 KHz w/filter | 100 Hz to 5.5 KHz | 200Hz to 4KHz | Not Stated | Yes |
| Max. Gain | 57 dB | 60-86 dB depending on model | Not Stated | Not Stated | Yes |
| Device Class | II | II | II | II | Yes |
| Manufacturer: | WORDCOMP INTERNAT. | Unitron | Radioear | Starkey Labs, Inc. | Yes |
| Classification Code: | 77LXB | Same | Same | Same | Yes |
| K-Number | Pending | K884288 | Unknown | K923784 | NA |