

FEB - 4 1997

K964245

**SUMMARY-- PRECISE, TYMPANETTE, AND XACTO IMPRESSION KIT  
SUBSTANTIAL EQUIVALENCE**

The above mentioned impression kits are designed to provide the tools necessary for a Hearing Health Professional to obtain an accurate imprint of an individual ear and ear canal. The Hearing Health Professional receives materials in the form of a kit, and is responsible for any mixing of materials, or assembly of components for usage.

Impression material is handled in bulk form, prior to being packaged in kits. This material, whether in bulk or kit form, is identical. The material in the impression kits are substantially equivalent to Audalin Liquid and Impression Polymer. (There is no 510(k) for the Audalin impression material as it is exempt because it was in commercial distribution prior to 5/28/96.) 1976?

**Impression Kits**

- Smooth Consistency
- Ease of Insertion
- Non-Allergenic Properties
- Pleasant Scent
- Quick Drying Time
- Ease in Clean Up

**Audalin Liquid/Impression Polymer**

- Smooth Consistency
- Ease of Insertion
- Non-Allergenic Properties
- Pleasant Scent
- Quick Drying Time
- Ease in Clean Up

10/18/96

**SAFETY AND EFFECTIVENESS SUMMARY - PRECISE, TYMPANETTE, AND XACTO IMPRESSION KITS**

**NAME OF DEVICE:** Precise, Tympanette and Xacto Impression Kits.

**TYPE OF DEVICE:** Impression Kits, -- Substantially equivalent to Audalin Liquid and Audalin Impression Polymer.

**INTENDED USE:** To obtain an accurate imprint of an individual ear and ear canal.

**FEATURES:** Smooth consistency, ease of insertion, non-allergenic properties, pleasant scent, quick drying time, easy clean up.

**ASSEMBLY:** Kits are assembled for Hearing Health Professionals, who are responsible for any mixing of materials or assembly of components for usage.

**TECHNICAL CHARACTERISTICS:** Material Safety Data Sheets are included for description of technical characteristics.

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