

MAY - 2 1997

K970952

SAFETY AND EFFECTIVENESS SUMMARY - PRECISE IMPRESSION KIT

NAME OF DEVICE: Precise Impression Kit.

TYPE OF DEVICE: Impression Kits, -- Substantially equivalent to the Silhouette™ Premium Impression System from Siemens Hearing Instruments, Inc. and the Matrics Impression System from Matrics, Inc.

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.

3/13/97