

K961082

TECHNA TONE Hearing Aids
350 N. Belt East #255
Houston, Texas 77060
(713) 820-9393
Fax #(713) 820-9590

MAY -7 1996

FDA 510(K) Submission
Summary of Safety & Effectiveness

TECHNA TONE intends to manufacture and market three different models of an air conduction hearing aid which will be used to amplify sounds for the hearing impaired. These devices will produce similar results and will be manufactured using the same industry standards thereby making it substantially equivalent to the post amendment devices currently marketed by Active Electronics. The attached comparison chart highlights the features of both manufacturers products for easy reference.

TECHNA TONE will receive an impression from the licensed dispenser or Audiologist and will mold a custom shell using polymer monomer resin in one of three colors.. A microphone, amplifier, power source, volume control, and receiver will be inserted. The components being used are industry standards and are currently used by many other hearing aid manufacturers. The final step of the manufacturing process is to run an ANSI S3.22.1987 strip to verify that the integrity of all electrical components meet the specifications stated.

After manufacture, the completed hearing instrument will be packaged in a polyethylene bag, enclosed inside a 1/2" foam protector and will then be placed in a corrugated cardboard box for shipment to the licensed Dispenser or Audiologist for final delivery to the end user. The outer corrugated box has not reached final development but will contain the following information:

Manufactured by: **TECHNA TONE**
350 N. Belt East #255
Houston, Texas 77060

Model#: _____
Serial #: _____
Customer Name: _____

The following inserts will be included in the corrugated box prior to shipment:

- 1. **TECHNA TONE USER'S MANUAL**
- 2. **Product Profile**
- 3. **ANSI Strip**
- 4. **Warranty Card**

Hearing aids are manufactured with 5 basic working components (microphone, amplifier, power source, volume control and receiver) inserted into an outer shell. The proposed TECHNA TONE aid will include these same components and will produce similar results as the predicate device, the only differences are really in the source of the components and the location of assembly. These differences will not affect the safety or effectiveness of the product.