



**Ear Technology Corporation**  
207 E. Myrtle Ave.  
Johnson City, TN 37601  
(615) 928-9060 (615) 928-1424 (FAX)

Manufacturers of:  
the EarTech™ family of hearing products  
and EarFree™ Cerumen Removal Systems

## 510 (k) Summary

K972776

Submitter:

Ear Technology Corp.  
207 E. Myrtle Avenue.  
Johnson City, TN 37601  
Contact: Rick Gilbert  
(423) 928-9060  
(423) 928-1424 fax

SEP - 8 1997

Prepared July 21, 1997

Trade Name: Dry & Store  
Common Name: Hearing aid drying appliance  
Classification Name: Accessory to Hearing Aid

A hearing aid drying appliance is an accessory for use by hearing aid users to remove moisture that collects in the hearing aid during normal use. Various products, most using a desiccant, have been in use for many years. Dry & Store uses a desiccant, a fan, and heat - all common technologies - to remove much of the moisture. The manufacturer makes no claims as to degree of dryness, humidity level claimed after a drying cycle, or any other claim that suggests a minimum performance level.

Along with drying, the product features a sanitizing cycle using a 4-watt ultraviolet bulb, commonly in use for a number of applications outside the hearing aid accessory market. The manufacturer does not claim sterilization, nor do we claim that use of our product will completely eliminate problems associated with hearing aid use. On the other hand, a dry atmosphere and use of ultraviolet light to provide an unkind environment for bacterial growth is well known.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Richard J. Gilbert, Jr.  
Director of Marketing  
Ear Technology Corporation  
207 E. Myrtle Avenue  
Johnson City, TN 37601

Re: K972776  
Dry and Store (Air Conduction Hearing Aid  
Accessory (Dryer))  
Dated: July 23, 1997  
Received: July 25, 1997  
Regulatory Class: I  
21 CFR 874.3300/Procode: 77 ESD

SEP - 8 1997

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K972776/A1

510(k) Number (if known): K972776

Device Name: Dry & Store

**Indications For Use:**

This product is used by hearing aid users as an accessory to remove moisture from their devices, usually overnight while they sleep.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

David A. Bergerson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K972776

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

SK-58