United Hearing Systems, Inc.
731B Norwich Road • P.O. Box 122 • Plainfield, CT 06374
Telephone (860) 564-4130 • Fax (860) 564-5724

K970828

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 28 1997

Name of Device: **UHS MicroNET Programmable Air Conduction Hearing Aids and Programmer**

Model Nos.: This hearing aid comes in your choice of models, as follows:

Full Concha --	**P901**
Demi Concha --	**P902**
Custom Canal --	**P903**
Mini Canal --	**P903m**
Low Profile --	**P906**
CIC CanalMate --	**P909**

All the above models are available in a choice of one of two circuits, the Etymotic DSD K-AMP circuit and the Gennum DSD-DynamEQ II circuit. The hearing aids are programmed using the UHS microNET Programmer, a hand-held device. The aids can be fit to hearing impaired individuals with mild to moderate hearing losses. Because of the range of the programming, the aid can fit most all audiogram configurations and has provisions for patients with low tolerance to loud sounds.

Each aid comes with a user's brochure and other labeling which will ensure that the hearing aids will be marketed in compliance with Federal hearing aid labeling regulations (21 CFR 801.420).

Performance characteristics are included with each aid. The performance characteristics were obtained using the test procedures outlined in ANSI S.22 (1987).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ralph Campagna
President
UNITED HEARING SYSTEMS, INC.
731B Norwich Road
P.O. Box 122
Plainfield, CT 06374

MAY 28 1997

Re: K970828
UHS microNET™Programmable Air
Conduction Hearing Aid Models
901, 902, 903, 906, and 909 fitted with the
Gennum EQ2-Band Amplifier Circuitry
Dated: March 4, 1997
Received: March 6, 1997
Regulatory Class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Campagna:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that electromagnetic interference from digital cellular telephones, as well as from other sources, is increasingly becoming a concern. Typically, this interference takes the form of a buzzing sound that can range from annoying to very loud and may render a hearing aid temporarily ineffective for the wearer. Because electromagnetic interference may affect your device, you may be asked to test for electromagnetic compatibility in the future. In this interim period, we encourage you to modify your device labeling to inform practitioners and users of the potential for electromagnetic interference. Please be aware that a 510(k) submission is required for any claims that infer that your device is compatible with potential sources of electromagnetic interference, such as "compatible with digital cellular telephones", and that data supporting such claims is necessary.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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 at (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

510(k) Number (if known):_____

Device Name: UHS microNET™ Programmable Air Conduction Hearing Aids Models 901, 902, 903, 906, and 909 Fitted with the Gennum EQ2-Band Amplifier Circuitry Programmer

Indications For Use:

A. General Indications:

The indication for use of the air conduction hearing aids in this submission is to amplify sound for individuals with impaired hearing. The devices are indicated for individuals with losses in the following category(ies). (Check appropriate space(s)):

Severity:	Configuration:	Other
x 1. Slight	x 1. High Frequency -Precipitously Sloping	x 1. Low tolerance To Loudness
x 2. Mild	x 2. Gradually Sloping	2._____
x 3. Moderate	x 3. Reverse Slope	3._____
4. Severe	x 4. Flat	
5. Profound	5. Other_____	

Restricted device (per 21 CFR 801.420 & 21 CFR 801.421)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970828