DANAVOX

Partners in Hearing Care

JUN 17 1997

K971032

Danavox 163 / 162 BTE

SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial equivalence for the Danavox 163 / 162 BTE to the predicate device, the Danavox Aura 510(k) No. K905692 is based on the following:

- This air-conduction behind-the-ear hearing instrument with body-worn processor is intended to amplify sound pressure waves and transmit the signal to the external ear through the medium of air to compensate for hearing losses from mild to severe.

- The device is powered by a standard hearing aid battery (Model 163 - type 13 , Model 162 - type 312) .

- The device is manufactured and delivered completely assembled to the hearing aid dispenser using materials and techniques widely used by other manufacturers of hearing devices.

- The intended use, performance specifications, functions and operations of the Danavox 163 / 162 BTE are essentially identical to that described in the 510(k) Premarket Notification for the Danavox Aura.

- The ability to program digitally the fitting parameters of the hearing device is the same as in the Danavox Aura as is the ability to change the characteristics of the sound processing and adjust the volume.

- The Danavox 163 / 162 BTE has the ability to retain up to three programs in memory, whereas the predicate device can retain four programs in memory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. Wayne Morris
Director of Operations
GN Danavox, Inc.
5600 Rowland Road, #250
Minnetonka, MN 55343

Re: K971032
DANAVOX Model 163/162 BTE Hearing Aids
Dated: March 20, 1997
Received: March 21, 1997
Regulatory Class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Morris:

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: Danavox Model 163/162 BTE

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
___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. _____
X 4. Severe	X 4. Flat	
___5. Profound	___5. Other_____	

B. Specific Indications (Only if appropriate.):
(Most psychoacoustic indications such as improved speech intelligibility in background noise, must be supported by clinical data.)

1.

2.

3.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971032

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