K974751

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Tranquil™ TRI-OE

MAR - 6 1998

TYPE OF DEVICE: I-T-E

INTENDED USE: A hearing Aid and/or Tinnitus Masker/Habituator

FEATURES: Class A Noise Generator, Class D Noise Generator, DSD K-amp programmable or Intrigue Programmable

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufactures

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3 2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control mechanical or electronic

POWER: Standard Size 312 battery

A USERS' MANUAL AND OTHER INFORMATION IS SUPPLIED WITH EACH MASKER/HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Tranquel TRI-COE

TYPE OF DEVICE: I-T-C

INTENDED USE: A hearing Aid and/or Tinnitus Masker/Habituator

FEATURES: Class A Noise Generator, Class D Noise Generator, DSD K-amp programmable or Intrigue Programmable

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufactures

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3 2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control mechanical or electronic

POWER: Standard Size 10A battery

A USERS' MANUAL AND OTHER INFORMATION IS SUPPLIED WITH EACH MASKER/HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Tranquel TRI-CIC

TYPE OF DEVICE: C-I-C

INTENDED USE: A hearing Aid and/or Tinnitus Masker/Habituator

FEATURES: Class A Noise Generator, Class D Noise Generator, DSD K-amp programmable or Intrigue Programmable

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufactures

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3 2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control mechanical or electronic

POWER: Standard Size 10A battery

A USERS' MANUAL AND OTHER INFORMATION IS SUPPLIED WITH EACH MASKER/HEARING AID.

ATTACHMENT I

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 1998

Roger P. Juneau
President
General Hearing Instruments, Inc.
P.O. Box 23748
New Orleans, LA 70183-0748

Re: K974751
Tranquil TRI-OB, TRI-COE & TRI-CIC Tinnitus Maskers /Hearing Aids
Dated: December 17, 1997
Received: December 19, 1997
Regulatory class: III
21 CFR 874.3400/21 CFR 874.3300
Procode: 77 KLW/77 ESD

Dear Mr. Juneau:

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.

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 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

510(k) Number (if known): K974751

Device Name: Tranquil^{tm} TRI-OE

Indications For Use:

No hearing loss or a mild to severe high frequency hearing loss where the patient exhibits a low tolerance to loudness or when the patient's response to tinnitus is characterized by intolerence. Specifically the inability to cope with head noises, anxiety, depression or the inability to function in daily life activities.
When cosmetics are not an issue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974751

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Restricted Device
Per 874.420 and 421

510(k) Number (if known): K974751

Device Name: Tranquil tm TRI-COE

Indications For Use:

No hearing loss or a mild to severe high frequency hearing loss where the patient exhibits a low tolerance to loudness or when the patient's response. to tinnitus is characterized by intolerence. Specifically the inability to cope with head noises, anxiety, depression or the inability to function in daily life activities.
When cosmetics are an issue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974751

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Restricted Device
Per 874.420 and 421

510(k) Number (if known): K974751

Device Name: Tranquil^{tm} TRI-CIC

Indications For Use:

No hearing loss or a mild to severe high frequency hearing loss where the patient exhibits a low tolerance to loudness or when the patient's response to tinnitus is characterized by intolerence. Specifically the inability to cope with head noises, anxiety, depression or the inability to function in daily life activities.
When cosmetics are a major issue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974751

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Restricted Device
Per 874.420 and 421