K984243 JAN 21 1999

TELEX

Telex Communications, Inc.

510(k) SUMMARY Item C

9600 Aldrich Avenue South
Minneapolis, Minnesota 55420 USA
Telephone 612-884-4051
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510(k) SUMMARY

Trade Name:	Telex Tinnitus-Companion, Models TC TRL and TC TRS
Common Name:	tinnitus masker
Classification Name:	Masker, tinnitus 77KLW
Equivalent to:	Starkey TM Air conduction Tinnitus Masker K963838

Description:

Intended use:	for use in treatment and control of tinnitus.
Features:	non-occluding Ultra-helix type shell, two power levels
Assembly:	assembled from standard components that are widely used by other hearing aid manufacturers.
Technical characteristics:	measured with Fonix™ 6500, 2cc coupler, "Spectrum Mode".
Fit:	typical frequency response as shown on specification filed with 510(k). Response can be tailored to the individual via audiological controls.
Controls:	Volume control, one Audiological Control (tone).
Power:	Standard hearing aid battery (312)

Comparison to predicate device: no significant difference.

Submitted by:

Tom Scheller
Chief Engineer
Hearing Instruments Group
Telex Communications, Inc.
9600 Aldrich Ave S.
Minneapolis, MN 55420
(612) 884-4051 voice
(612) 884-0043 fax

Contact: Tom Scheller
Prepared: 14 December, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1999

Tom Scheller
Chief Engineer
Hearing Instruments Group
Telex Communications, Inc.
9600 Aldrich Ave. S.
Minneapolis, MN 55420

Re: K984243
Telex Tinnitus-Companion, Models TC TRL and TC TRS
Dated: November 24, 1998
Received: November 27, 1998
Regulatory class: III
21 CFR 874.3400/Procode: 77 KLW

Dear Mr. Scheller:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Item A

510(k) Number (if known): K984243

Device Name: Telex Tinnitus-Companion, Models TC TRS and TC TRL

Indications For Use:

A. General Indications:

The indication for use of the tinnitus masker in this submission is for use in treatment and control of tinnitus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984243

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 901.109)