K982683

TELEX

OCT 6 1998

Telex Communications, Inc.

510(k) SUMMARY

9600 Aldrich Avenue South
Minneapolis, Minnesota 55420 USA
Telephone 612-884-4051
Fax 612-884-0043

Trade Name: Telex Select 1-40 with Adaptive Compression®
Common Name: FM at-the-ear Auditory Trainer
Classification Name: Hearing Aid, Group and Auditory Trainer, 77EPF
Equivalent to: Telex Model Select 2-40 K961143

Description:

Intended use: to amplify and transmit sound to the ear.
Features: Adaptive Compression; True FM Override (patent pending); function switch allows hearing aid only, FM reception only, or both;
Assembly: assembled from standard components that are widely used by other hearing aid manufacturers.
Technical characteristics: technical specifications comply with S3.2-1987 ANSI standards.
Fit: frequency response per S3.2-1987 ANSI standard as shown on specification filed with 510(k).
Controls: Volume control, Mode Switch, Audiological Controls (output and tone).
Power: Standard hearing aid battery (675)

Comparison to predicate device: identical to the Telex Select 2-40, except for that it does not contain two channel switch selectable FM reception, user replaceable channel crystals, and an additional audiological control (gain).

Submitted by:

Tom Scheller
Chief Engineer
Hearing Instruments Group
Telex Communications, Inc.
9600 Aldrich Ave S.
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(612) 884-4051 voice
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Contact: Tom Scheller
Prepared: 28 July, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1998

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

Re: K982683
Telex Select 1-40 FM Auditory Trainer
with Adaptive Compression®
Dated: July 28, 1998
Received: July 31, 1998
Regulatory class: II
21 CFR 874.3320/Procode: 77 EPF
21 CFR 874.3300/Procode: 77 ESD

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 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,

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

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Indications for Use

Item A

510(k) Number (if known): K982683

Device Name: Telex Select 1-40 FM Auditory Trainer with Adaptive Compression®

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	√	1. High Frequency	Low tolerance to Loudness
	2. Mild	√	2. Gradually Sloping	
√	3. Moderate	√	3. Reverse Slope	
√	4. Severe	√	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.)

The Telex Select 1-40 BTE FM System is best suited for students of middle school age and older who have a moderate to profound hearing loss. It may be appealing to older students that have rejected FM amplification because of the stigma associated with body-worn auditory trainers.

(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 K982683

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