APR 29 1998

510(k) Summary

Ultramind International Ltd.

Ultramind Biofeedback System with de-STRESS Software

510(k) Number K 980373

Submitter's Name:

Ultramind International Ltd.
Building 35A, Sheba Medical Center
Tel Hashomer 56201, Israel
Tel: 972-3-535-6535
Fax: 972-3-535-6880
E-mail: telsh@ultramind.co.il

Contact Person:

Shoshana Friedman
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373, Israel
Tel: 972-9-771-8130
Fax: 972-9-771-8130

Trade Name:

Ultramind Biofeedback System with de-STRESS Software

Classification Name:

Biofeedback Device

Classification:

The FDA has classified biofeedback devices as a class II device (product code 84 HCC) and it is reviewed by the Neurology Devices Branch.

Predicate Devices:

Ultramind RelaxPlus™ System (K951213)

Performance Standards:

No performance standards applicable to the biofeedback devices have been established under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the ***Ultramind Biofeedback System*** complies with IEC 601-1 and IEC 601-1-2.

Indication for Use:

The ***Ultramind Biofeedback System with de-STRESS Software*** is a biofeedback system designed to be used for relaxation training.

Device Description:

The ***Ultramind Biofeedback System*** comprises a sensor which transmits changes in the stress/relaxation levels to a receiver. In turn, the receiver feeds the information on line to a computer which, by means of the ***de-STRESS Software***, is able to analyze, record, and select data as well as display instructions on how to use the system for the purpose of learning the art of relaxation.

The user wears on his/her finger a small plastic mold that contains two electrodes. The electrodes detect minute physiological changes, measured in terms of relative electro-dermal activity (EDA) or galvanic skin response (GSR), that reflect the user's conscious, subconscious or physical state. This information is transmitted by cordless link to a personal computer and is displayed in the form scientific graphs, or used to drive animation.

The animation depends on the user's state of mind, i.e., the user is able to change the animation by his/her thoughts or emotions. Through this "play", as the user learns to correlate between thoughts and emotions and the response of the computer game, he/she learns to control physiological responses - even in the realm of the autonomic nervous system.

After practice, the user retains the newly-learned capabilities, and can use them at will without the system. The learning process is accelerated through use of advance psychological techniques which enable the user to learn with both hemispheres of the brain, with the intellect and the subconscious.

Substantial Equivalence:

The ***Ultramind Biofeedback System with de-STRESS Software*** is substantial equivalent to the ***RelaxPlus™ System*** cleared under K951213 (Ultramind International Ltd.). In fact, the ***Ultramind Biofeedback System with de-STRESS Software*** is a modification of the ***RelaxPlus™ System*** incorporating a set of minor changes in software, hardware, and design of the user interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1998

Ms. Shoshana Friedman
Ultramind International Limited
C/O Push-Med Limited
117 Ahuzah Street
Ra'ananna, Israel 43373

Re: K980373
Trade Name: Ultramind Biofeedback System
with de-STRESS Software
Regulatory Class: II
Product Code: HCC
Dated: January 25, 1998
Received: January 30, 1998

Dear Ms. Friedman:

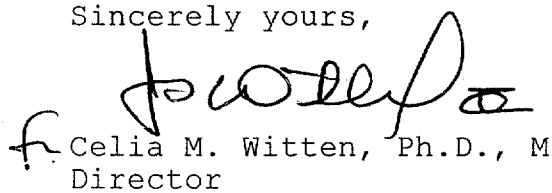
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K980373

Device Name: ***Ultramind Biofeedback System with de-STRESS Software***

Indications for Use: The ***Ultramind Biofeedback System with de-STRESS Software*** is a biofeedback system designed to be used for relaxation training.

(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, Ear, Nose and Throat, and Radiological Devices

510(k) Number K980373

Prescription Use _____ OR Over the Counter Use X
(Per 21 CFR 801.109)