K051684

MAR 17

510(k) Summary of Safety and Effectiveness

Submitter:

Company Name:	Exercise Your Eyes, Inc.
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Mailing Address:	Exercise Your Eyes, Inc. P.O. Box 80904 Rancho Santa Margarita, CA 92688
Phone:	(949) 888-3781
Registration:	Pending
Manufacturing Site:	Providence Enterprise Limited Unit 13-15, 6/F. Grand City Plaza No. 1, Sai Lau Kok Road Tsuen Wan, N.T. Hong Kong. Ph: 11 852-2415 2293 Fax: 852-2415 2286
Contact:	Albert Lee Providence Enterprise Limited Email: albert@providence.com.hk Mobile Ph: 011- (852) 9192 9731 HK Office: (852) 2415 2293 China Plant: 011 (86) 755-8465 4646

Official Correspondent: Jacob Liberman, OD, PhD.

Address:	133 KA Drive Kula, Hawaii
Phone:	(808) 876-1926

Device Identification:

Proprietary Name:	EYEPORT Vision Training System
Common Name:	Vision Training Device
Classification Name:	Fixation Device

Side-by-side comparison of the EYEPORT, Gruss Electro Wand and Vis-Flex

	EYE	Gruss Electro Wand	Vis-Flex
Indications for Use	The EYEPORT is indicated for the treatment of poor accommodative and vergence facility, convergence insufficiency and large accommodative lag (in non-presbyopic subjects).	The Gruss Electro Wand was used for the diagnosis and treatment of convergence excess, convergence insufficiency, poor fixations, strabismus, and suppression.	The Vis-Flex is used for training ocular motor skills such as tracking, pursuits, saccadics, fixations, accommodation and convergence.
Target Population	Healthy Individuals	Healthy Individuals	Healthy Individuals
Design	Plastic bar with alternating red and blue lights	Metal bar with lights	Plastic bar with lights
Anatomical Sites	Eyes	Eyes	Eyes
Fundamental Technology	Individual light sources turn on and off to create visual stimuli	Individual light sources turn on and off to create visual stimuli	Individual light sources turn on and off to create visual stimuli
Energy Source	AC adaptor or AA batteries	AC adaptor	AC adaptor
Where Used	In home or optometrist office	In optometrist office	In optometrist office

The only significant differences between the EYEPORT and the two mentioned predicates are overall length of the light bar and color of the light sources. The EYEPORT is 36" long, the Gruss Electro Wand is 27" long and the Vis-Flex is 48" long. The differences in the length are primarily based on practitioner preference.

The EYEPORT makes use of alternating red and blue lights, while the Gruss Elecrtro Wand used and Vis-Flex use only red LED's. The alternating red and blue lights used in the EYEPORT make use of the phenomenon of chromatic aberration to gently rock accommodation and convergence, as the lights are fixated. The red lights used in the Gruss Electro Wand and Vis-Flex function only as fixation targets,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2006

Exercise Your Eyes™ (EYE), LLC
c/o Jacob Liberman, O.D., Ph.D.
133 KA Drive
Kula, HI 96790

Re: K051684
Trade Name: EYEPORT™ Visual Training System
Regulation Number: 21 CFR 886.1290
Regulation Name: Fixation Device
Regulatory Class: Class I
Product Code: NXR
Dated: March 6, 2006
Received: March 7, 2006

Dear Dr. Liberman:

This letter corrects our substantially equivalent letter of March 17, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051684

Device Name: EYEPORT Vision Training System

Indications For Use: The EYEPORT is indicated for the treatment of poor accommodative and vergence facility, convergence insufficiency and large accommodative lag (in non-presbyopic subjects).

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051684