K042529 1/2

OCT 6 - 2004

E 510(k) Summary

Submitter's Name:	**Fall Prevention Technologies, LLC**
Submitter's Address:	2300 NW Corporate Blvd. Suite 141 Boca Raton, FL 33431
Submitter's Telephone:	561-995-8883
Contact Name:	Keith Kravitz
Date Summary was Prepared:	August 10, 2004
Trade or Proprietary Name:	BalanceBack VNG System
Common or Usual Name:	VNG
Classification Name:	Nystagmograph (21 CFR 882.1460), product code GWN, Class II

Predicate Devices:

Device Name	510(k) Number
Eye Dynamics, Inc. House Infrared/Video Electronystagmographic (ENG) System	K925111
Sensomotoric Instruments, Inc. 2d Vog – Video-Oculography System	K972243

Indications for Use:

The BalanceBack VNG device is intended for recording, viewing, and analyzing eye movements in support of identifying balance disorders in human subjects. The VNG is intended for use only by trained physicians or clinicians in an appropriate doctor's office or health care facility. This device provides no diagnoses nor does it provide diagnostic recommendations.

Description of the Device and Summary of the Technological Characteristics:

Eye movements have long been known to provide important clues to the identification and location of balance disorders. Physicians and other clinicians employ the VNG system to conduct a set of established, well-known and well-documented eye movement tests. The results of the VNG eye movement tests are combined with other clinical information so that the attending clinicians may render findings on the health of the patient's primary balance sensors and related balance processing system.

Using the VNG, clinicians guide patients through a series of eye movement tests. A testing battery (i.e., an *examination*) typically consists of all eight tests supported by the VNG: caloric, positional, Hallpike, gaze, saccades, smooth pursuit, optokinetic, and

high-frequency head shake. The attending physician may select one, several, or all tests, and has full flexibility in determining the sequence of the tests to be performed.

The patient under examination wears the VNG goggles. The goggles contain one IR light source and one IR camera for each eye. The IR video cameras sense the infrared signal reflected from the eyes and create a continuous monochromatic (grayscale) video motion picture stream of the eyes. The infrared signal is used because the human eye cannot detect the presence of the infrared signal and therefore this illumination does not create perturbations in measurements of eye movement. Measurements may therefore be made both in the presence and in the absence of visible light, thus providing clinicians with maximum flexibility for making measurements in a wide variety of situations.

The video stream from the IR cameras is digitized and transferred into the memory of the digital computer where signal processing software tracks, records, analyzes and displays eye movements for the attending clinician. The VNG system makes appropriate calculations and presents reports of well-known and well-documented parameters associated with each eye movement test.

Some eye tests require the patient to follow a visual stimulus. A projector, controlled by the VNG software, displays stimuli on any light-colored surface, such as a wall or projection screen. The goggles and VNG software record the patient's eye movements while he/she follows the stimulus.

Substantial Equivalence:

The BalanceBack VNG device is substantially equivalent to the Eye Dynamics, Inc. House Video/Video Electronystagmographic (ENG) System and the Sensomotoric Instruments, Inc. 2d Vog – Video-Oculography System. All three devices support the recording, viewing, and analyzing of horizontal and vertical eye movements to assist in the identification of balance disorders in human subjects. These devices use similar technology, including workstation, computer monitor, masks mounted with video cameras, and software, for performing caloric, positional, Hallpike, gaze, saccades, smooth pursuit, and optokinetic examinations. All three devices use the same sampling rate and similar illumination wavelengths.

Testing:

Various tests of the hardware and software are being performed to verify system specifications. Verification procedures with pass/fail criteria were developed to ensure that the product met all the specified requirements. As part of this verification, a certified body shall conduct tests to determine the conformance of the device to the recognized standards shown below. The device will not be marketed or sold until it has been certified to pass these tests.

- ANSI Z-136.1 (2000)
- IEC 60601-1 (2004)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)
- UL 60601-1 (2003)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Fall Prevention Technologies, LLC
c/o Mr. Daniel W. Lehtonen
Staff Engineer - Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K042529
Trade/Device Name: BalanceBack VNG System
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: II
Product Code: GWN
Dated: September 16, 2004
Received: September 17, 2004

Dear Mr. Lehtonen:

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 application (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 such 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 (240) 276-0115. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

D Indications for Use Statement

Ver/ 3 – 4/24/96

Applicant: Fall Prevention Technologies, LLC

510(k) Number (if known): _____

Device Name: BalanceBack VNG System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042529

Prescription Use _____ Over the Counter Use _____
per 21 CFR 801.109