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510(k) Summary - 807.929(c)

Sponsor: - 807.92(a)(1)

Submitter:

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Date of preparation:

Tuesday, August 26, 2008

Device Name - 807.92(a)(2)

Trade name of device:

DizzyFIX

Common name:

Device for assisting in the performance of the particle repositioning maneuver

Classification name:

Unclassified – Product Code LXV - Apparatus, vestibular analysis

Predicate Devices/Equivalence Claim: - 807.92(a)(3)

The DizzyFIX appears equivalent to the predicate devices listed below. It is intended to assist in the treatment of the vestibular disorder - "Posterior canal Benign Paroxysmal Positional Vertigo (BPPV)"

Predicate Device #1

Apparatus, vestibular analysis (LXV)

510(k) Number: K071973

Device Name:EPLEY OMNIAX

Applicant:VESTICON

2203 NE Oregon Street

Portland, OR 97232

Predicate Device #2

Apparatus, vestibular analysis

510(k) Number: K070676

Device Name:KOREBALANCE (KINESTHETIC ABILITY TRAINER)

Applicant:SPORTKAT, LLC

1497 Poinsettia Ave. Ste. 157

Vista, CA 92083

Predicate Device #3

Apparatus, vestibular analysis

510(k) Number: K070085

Device Name BALANCE REHABILITATION UNIT (BRU)

Applicant:MEDICAA (URUGUAY) S.A.

1101 South Capital Texas Hwy.

Suite f254

Austin, TX 78746

Summary of Equivalence:

Characteristic Indications	DizzyFIX 081602	Omni-ax 071973	KOREBalance 070676	BRU 070085
Intended Use	The DizzyFIX is intended to act as a guide to the therapeutic maneuver for the treatment of vertigo and dizziness, specifically BPPV .	The Omni-ax is intended as diagnostic and treatment device for vertigo and dizziness, including BPPV	The KORE Balance platform is intended for the treatment of dizziness and vertigo from a variety of vestibular disorders.	The BRU is a diagnostic and therapeutic device for a variety of vestibular disorders.
Patient Use	Performed at home in a doctors or physiotherapist office.	Performed by physicians or technicians	Performed by technicians or physiotherapists.	Performed by technicians or physiotherapists.
Principle of Operation	A plastic tube with fluid and a	The device is essentially a	The device is a balance platform	The device is a balance platform

	ball visually guides patients through the maneuver for the treatment of BPPV	360 degree rotary chair which can take patients through the treatment maneuvers for BPPV		
Mode of operation	Non-sterile, non-battery powered device worn on the head which guides an exercise	Non-sterile, powered device, in which a patient sits and is moved	Non-sterile, powered device on which a patient stands	Non-sterile, powered device on which a patient stands
Major Components	Plastic, Clear Fluid (Oil), Cloth Hat	A sphere in which a chair is situated and can move in 360 degrees	Primarily a platform on an inflated bladder	Primarily a platform with gimbals which can rotate in 2 planes

Device description: - 807.92(a)(4)

The DizzyFIX is a small, non powered, non-sterile head worn device which can assist in the performance of the treatment exercises for vertigo.

The most common cause of dizziness related to the ear is called Benign Paroxysmal Positional Vertigo (BPPV). BPPV is a chronic and recurrent vestibular problem. Fortunately, there is an effective treatment for BPPV. Specifically, the “Particle Repositioning Maneuver” is a therapeutic exercise which involves rolling the head and body in a specific series or angles to move loose particles out of inner ear areas which cause dizziness. These maneuvers treat most (80-95%) cases of BPPV and a device is not mandatory to perform these exercises. However, a device may be a useful component of these maneuvers to help guide them. This exercise maneuver is extensively documented as both safe and effective however it can be difficult to perform correctly without some form of guidance. The DizzyFIX is a device which assists in the performance of a correct “Particle Repositioning Maneuver”. Whether being used by a patient at home, a doctor or other health professional, this device helps to treat BPPV by encouraging the correct angles and duration for conducting both diagnostic and treatment exercise maneuvers. With the DizzyFIX, persons who suffer from BPPV can repeat the repositioning exercises at home as often as needed to achieve resolution of symptoms.

Device Function and Scientific Concepts:

The dizziness of Benign Positional Vertigo is thought to be due to debris (otoconia) trapped in fluid within the balance organ. These crystals cause spinning dizziness when disturbed by head motion. BPPV is brought on by

certain head positions. Patients often experience it several times a day during routine activities and frequently when they wake from sleep. The most effective treatment involves moving the debris away from the sensitive posterior labyrinth by a series of defined exercises first developed by Brandt and Daroff (Brandt Daroff Exercises) and later refined by Epley in 1988. The debris will eventually re-accumulate in the posterior canal and symptoms of BPPV frequently (~60%) recur within a few months or years. BPPV is now thought to be a chronic condition which should be managed at home and in the community. Generally recurrent symptoms can be successfully treated by repeated Brandt and Daroff exercises or Epley maneuvers (>80%).

The 'DizzyFIX' device helps with treatment of BPPV at home, by guiding patients through the series of vestibular exercises known as the Particle Repositioning Maneuver. In our clinical trials 88% of patients successfully treated their BPPV by performing these exercise maneuvers with the assistance of the DizzyFIX device. There were no significant side effects.

Physical and performance characteristics:

The DizzyFIX consists of a specially curved acrylic tube containing a non-toxic viscous fluid and a bead. The entire device is about the size of a person's fist and weighs only a few hundred grams. Factors such as fluid viscosity and tube shape were carefully designed so that motion of the bead within the tube guides the patient accurately through the series of vestibular exercises.

The device clips onto the mid-brim of any hat such that it is visible to the wearer. Beginning with the bead at one end of the tube, the patient tilts his or her head at appropriate angles and time intervals to slowly move the bead to the other end of the tube. Thus, there is real-time feedback to the patient. If the bead arrives at the other end of the tube, the exercise maneuvers have been performed correctly. The exercise maneuver can be repeated as often as needed. This exercise maneuver is the **same** treatment provided by specialist physicians for the treatment of BPPV. The DizzyFIX in and of itself does not treat BPPV. Rather, it assists in the exercise while the user performs the standard exercise maneuver. The device provides feedback which enables non-specialists and patients to perform the exercise maneuver correctly. Thus, the DizzyFIX can be used to assist in the treatment of BPPV.

Statement of Intended Use: - 807.92(a)(5)

The DizzyFIX is indicated for the treatment of vertigo where a physician has diagnosed posterior canal BPPV and recommended one of the exercise variations which are used to treat this type of vertigo. The DizzyFIX should be used as a component to assist in correct performance of therapeutic exercises for the treatment of vertigo.

The DizzyFIX is designed to be used in a variety of clinical and home settings

The DizzyFIX has been proposed for prescription use.

Technological Characteristics - 807.92(a)(6)

Several legally marketed predicates for the DizzyFIX device exists in the category of Physical Medicine.

- 1) Omniax – This device employs a chair mounted inside an omni-directional sphere allowing the patient to be taken through the correct execution of vestibular exercises.

The DizzyFIX employs a head-worn device for the purposes guiding the patient through the correct execution of vestibular exercises

- 2) The KORE Balance unit employs a plastic bladder under a platform to permit vestibular exercises and encourage balance and stability.

The DizzyFIX is a plastic device designed to guide the user through a series of movements intended for the treatment of BPPV and return to normal balance.

- 3) BRU – Balance platform is a multi-axial platform upon which the patient stands which is intended to diagnose and help treat a variety of vestibular disorders.

The DizzyFIX is plastic fluid filled tube designed to provide interactive feedback to the user about their posture and angulation such that they may perform a correct treatment maneuver for the treatment of vestibular disorders.

Each of the above predicates assists in the diagnosis and or treatment of a variety of vestibular disorders. The DizzyFIX is similar in that it guides the user through a series of movements in order to complete the treatment maneuver for a vestibular disorder, BPPV. Further it provides feedback on that performance. The DizzyFIX is indicated as an assistance device for the treatment of BPPV. The DizzyFIX device consists of a transparent tube filled with mineral oil. The device contains a bead that freely travels within the mineral oil. The tube is permanently sealed at both ends. The device has a clip which facilitates its attachment to the included hat such that it is visible to the user. The hat has a strap such that it is affixed snugly to the users head. The device, tube and bead have characteristics such that only by performing a correct vestibular exercise might the bead move from one end of the tube to the other.

Non-clinical and Clinical Tests - 807.92(b)

Non-clinical Tests Discussion - 807.92(b)(1)

The non-clinical testing included

- Performance testing of the device regarding the movement of the particle
- Tolerance testing of the device prior to breakage, and testing regarding the shatter characteristics of the device
- Testing of the integrity of the tube to prevent leakage at various temperatures
- Testing of the device clip such that it would maintain connection with the hat during the maneuver
- Tests of the hat's strap to determine whether it would prevent the hat from falling off the user's head during the maneuver
- Testing of the instructions and quick reference card such that users with a high school education might be able to understand the directions regarding the correct use of the device

Clinical Tests Discussion - 807.92(b)(2)

The DizzyFIX is a new application of well-known but relatively recent scientific discoveries dealing with the underlying cause of BPPV(1). A summary of the previously published background research used to conceive the DizzyFIX can be found below in section (a). Section (b) details the clinical trials applied to the new device. Section (c) details the conclusions of the non-clinical and clinical data.

(a) Scientific evidence relied on in the application

BPPV is caused by free floating particles in the human inner ear(1). These particles cause vertigo when in the posterior semi-circular canal(2;3). Simple repositioning of these particles through a series of maneuvers can alleviate the symptoms of vertigo(4), although it does not permanently rid the patient of these loose particles. In order to assist people in the performance of the repositioning maneuver a new head worn device was designed. The design of the device depended very heavily on the known anatomical and physical properties of the human balance organ, the vestibular apparatus (fig 1). In order to create an intuitive and accurate device design, a number of aspects had to be carefully

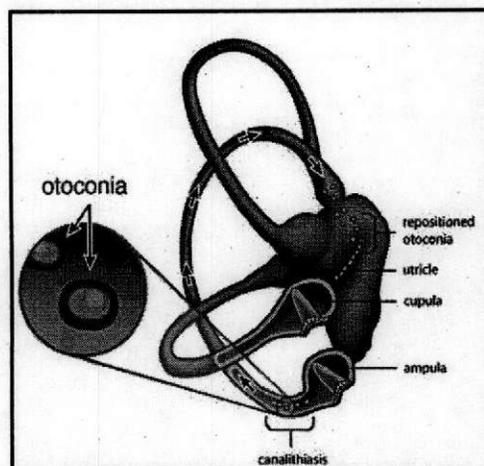


Figure 1: Human Vestibular Apparatus

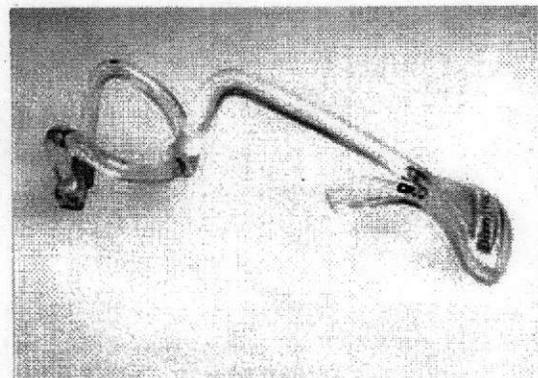


Figure 2: The DizzyFIX Device

considered(5-7). The viscosity and flow dynamics of the labyrinth had to be examined. A previously published mathematical and biomechanical model of the vestibular apparatus was consulted to determine the required biometric parameters. Clinical aspects such as latency of onset of vertigo, patient anxiety and safety also had to be considered. The device was designed such that only by performing a maneuver essentially similar to Epley's(2) maneuver, for the treatment of BPPV, would it register success. The overall design had to be both simple and able to perform its function bilaterally. The device in figure 2 provides relevant and real time feedback to both patient and physicians during the performance of a particle repositioning maneuver.

Reference List

- (1) Parnes LS, McClure JA. Free-floating endolymph particles: a new operative finding during posterior semicircular canal occlusion. *Laryngoscope* 1992 September;102(9):988-92.
- (2) Epley JM. The canalith repositioning procedure: for treatment of benign paroxysmal positional vertigo. *Otolaryngol Head Neck Surg* 1992 September;107(3):399-404.
- (3) Epley JM. Particle repositioning for benign paroxysmal positional vertigo. *Otolaryngol Clin North Am* 1996 April;29(2):323-31.
- (4) Epley JM. Canalith repositioning maneuver. *Otolaryngol Head Neck Surg* 1994 November;111(5):688-90.
- (5) Rajguru SM, Ifediba MA, Rabbitt RD. Biomechanics of horizontal canal benign paroxysmal positional vertigo. *J Vestib Res* 2005;15(4):203-14.
- (6) Rajguru SM, Ifediba MA, Rabbitt RD. Three-dimensional biomechanical model of benign paroxysmal positional vertigo. *Ann Biomed Eng* 2004 June;32(6):831-46.
- (7) Squires TM, Weidman MS, Hain TC, Stone HA. A mathematical model for top-shelf vertigo: the role of sedimenting otoconia in BPPV. *J Biomech* 2004 August;37(8):1137-46.
- (8) Sridhar S, Panda N. Particle repositioning manoeuvre in benign paroxysmal positional vertigo: is it really safe? *J Otolaryngol* 2005 February;34(1):41-5.

(b) Description of clinical tests performed:

Three clinical trials were performed (University of Western Ontario, London, Ontario, Canada IRB# 11214E, 12524E, 11547). A summary of the results and conclusions follows.

Supplementary Data: Study 1:



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Clearwater Clinical Limited
c/o Matthew Bromwich, MD.
CEO Clearwater Clinical
100 – 111 5th Avenue SW
Suite 258
Calgary, Alberta
Canada, T2P 3Y6

SEP 19 2008

Re: K081602
Trade/Device Name: DizzyFix
Regulatory Class: Unclassified
Product Code: LXV
Dated: August 26, 2008
Received: September 3, 2008

Dear Dr. Bromwich:

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.

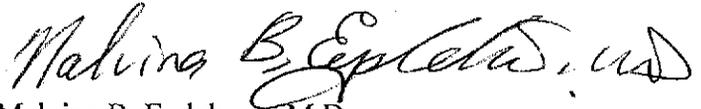
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

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): K081602

Device Name: DizzyFIX :

This statement is consistent with product labeling and instructions for use

Indications:

1. Patients with a diagnosis of Posterior Canal Benign Paroxysmal Positional Vertigo (BPPV) who exhibit:
 - a. Momentary spinning dizziness,
 - b. Which lasts seconds to minutes,
 - c. Which is associated with position change

Clinical settings

1. Physician offices
2. Hospitals
3. Long Term, Urgent and Emergent care facilities
4. Patient's homes
5. Allied Health and Complementary Health clinics and offices

Target population

1. Adults (age >18)
2. For use by patients or health practitioners

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

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Page 1 of 1



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K081602