September 14, 2018

DizzyDoctor® Systems, LLC
% Mark Job
Responsible Third Party Reviewer
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K182214
Trade/Device Name: DizzyDoctor® System 1.0.0
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: June 2, 2018
Received: August 15, 2018

Dear Mark Job:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182214

Device Name
DizzyDoctor® System 1.0.0

Indications for Use *(Describe)*
The DizzyDoctor® System 1.0.0 Eye Movement Monitor is indicated for use in the medical office, and in the home setting for monitoring patients with a diagnosis of dizziness caused by peripheral vestibular disorders who are under the supervision of a physician. The device detects abnormal eye movements in response to standard positional maneuvers by recording, tracking, storing and displaying vertical, horizontal and torsional eye movements. This device provides no diagnosis and does not provide diagnostic recommendations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date of Summary Preparation: 06/02/2018

1. Submitter Information

DizzyDoctor® Systems, LLC
7625 Mesa College Drive, Suite 200A
San Diego, CA 92111

Tel: (858) 223-2172
Contact: Ian Purcell MD, PhD

2. Device Identification

Proprietary Name:	DizzyDoctor® System 1.0.0
Common Name:	Eye Movement Monitor
Classification Name:	Nystagmograph (21CRF 882.1460)
Product Code:	GWN
Device Class:	Class 2
Panel:	Neurology

3. Predicate Devices: VisualEYES Video Eye Monitor; K964325; 07/15/1997; Micromedical Technologies.

Indications for Use: The DizzyDoctor® System 1.0.0 Eye Movement Monitor is indicated for use in the medical office, and in the home setting for monitoring patients with a diagnosis of dizziness caused by peripheral vestibular disorders who are under the supervision of a physician. The device detects abnormal eye movements in response to standard positional maneuvers by recording, tracking, storing and displaying vertical, horizontal and torsional eye movements. This device provides no diagnosis and does not provide diagnostic recommendations.

Device Description: Dizziness and postural instability are common in patients in Otolaryngology practice. Accurate diagnosis and choice of treatment is hampered by difficulties in obtaining thorough histories and perceptions that physical examination is complex. The DizzyDoctor® System 1.0.0 broadens physician access to video recordings of abnormal eye movement disorders with an easily operated device for in-office use by health professionals and for in-home use by patients experiencing exacerbating episodes of dizziness outside the office setting.

Using mobile and web-based technology, The DizzyDoctor® System 1.0.0 allows recording of patient of abnormal eye movements in response to standard head positions used for monitoring peripheral vestibular disorders such as Benign Paroxysmal Positional Vertigo. It consists of Vertigo Recording Googles (VRG) with a secure holder for the patient's iPhone, an iPhone Application for step-by-step audio instructions for medically-recognized Dix-Hallpike maneuvers, gyroscopic feedback for enabling correct head positioning, and accurate video-recording of eye movements in response to standard head positions used for assessing balance disorders.

The VRG secure docking station for the iPhone which aligns with the patient's pupil. The VRG has no direct electrical connection with external devices or equipment, and uses light from two LEDs during

recording sessions. The VRG uses a standard iPhone compatible macro lens to adjust the focal length of the iPhone camera lens, and secures with a flexible headband.

Key components of the patient's iPhone support the DizzyDoctor® System 1.0.0 including: an accelerometer and gyroscope, a video camera, storage of video recordings, audio voice/speaker system for real-time interaction with the patient, standard software for downloading and playing mobile applications from external App vendors, software for web-based processes including uploading stored videos.

The DizzyDoctor® Mobile App provides audio support for step-by-step procedures in recording eye movements in relation to positional changes during self-testing, The DizzyDoctor® System is supported by a comprehensive web-based platform for secure patient and physician registration, as well as uploading, processing and downloading videos from the professional- and self-testing for abnormal eye movements. Processed videos are accessed and viewed by physicians on their desk-top office computers.

VisualEyes Video Monitor	**DizzyDoctor® System 1.0.0 eye movement monitor**	**Assessment of Substantial Equivalence**
Anatomical Site: Human Eye	Human Eye	Same
Intended Use: Support evaluation and diagnosis of vestibular disorders from observation of eye movements from various stimuli	Support evaluation and diagnosis of vestibular disorders using standard positional maneuvers.	Same with respect to stimuli from positional maneuvers.
Indications for Use: The Eye Movement Monitor is used to observe eye movements from various stimuli used in vestibular diagnostic testing. It allows observation of horizontal, vertical and torsional eye movements. The Eye Monitor is mainly used to visually detect nystagmus positional maneuvers (e.g. Hallpike positional tests) or caloric tests). The device is especially useful in situations where the operator needs to observe the patient's eyes to distinguish nystagmus from artifacts. These observations are currently done using Fresnel lenses. The eye movement could also be recorded on suitable media (e.g., video tape) to provide documentation for any diagnosis based on observation of the Eye Monitor.	The DizzyDoctor® System 1.0.0 is indicated for use in the medical office, and in the home setting for patients with a diagnosis of dizziness caused by peripheral vestibular disorders who are under the supervision of a physician. The device detects abnormal eye movements in response to standard positional maneuvers by recording, tracking, storing and displaying vertical, horizon-tal and torsional eye move-ments. This device provides no diagnosis and does not provide diagnostic recommendations. Caution: Federal law restricts this device to sale by or on the order of a physician.	Substantially equivalent, except for the following differences. DDS 1.0.0 is intended for use in the medical office as well as by the patient in the home setting, as prescribed by the patient's doctor. The predicate device is not used in the home setting. DDS 1.0.0 is indicated for monitoring in patients with a diagnosis of peripheral vestibular disorders. DDS 1.0.0 does not support caloric testing; the predicate can. DDS 1.0.0 is a monocular device; the predicate is monocular and binocular. DDS 1.0.0 uploads videos of eye movement testing in the medical office or home settings directly to the DDS website for viewing by patients or patient's

		physician. For the predicate access is limited to the doctor, and remote access to remote in-home testing observations is not possible.
Intended Use: For observing eye movements during vestibular testing to support diagnostic testing of vestibule-ocular disorders.	For observing eye movements during vestibular testing to support diagnostic testing of vestibule-ocular disorders.	Substantially equivalent
Mechanical Construction: A light occluding goggle frame on which a small camera views the eye.	A light occluding goggle frame on which a small camera views the eye.	Substantially equivalent
Method of Viewing: Monocular or binocular LED side-lights Built in light shielding to block external light Viewed by direct observation optionally on video tape with separate device	Monocular LED side lights built into goggle Built-in light shielding to block external light Viewed on physician's office computer or laptop and patient's computer	Substantially equivalent
Power Source/Control: Mains/electrical outlet On/off button switch on goggles to start, stop and abort recordings during Dix-Hallpike and Positional Tests.	CR2 3V battery Button switch on googles to turn LED illumination on/off. Button on iPhone mounted on google allows on/off control during recording sessions.	Substantially equivalent
Camera: Cameras mounted on top of goggles and close to the forehead	Camera is in patient's or physician's iPhone, which is affixed at eye level eye to the goggle's Mounting Plate that aligns the iPhone camera to the patient's eye.	Substantially equivalent
Remote Access to Recordings: Not available	Remote access to eye movement videos recorded in the home setting through uploads from the patient's iPhone to the DDS website which can be down-loaded by patients and their physicians.	Different

Human Factors: Physician or technician guided testing in the medical office	Physician or technician guided testing for first use of the VRG, and helper-guided testing for in-home setting	Substantially equivalent For remote recording in the home setting, the patient's helper is trained at the doctor's office, and supported by audio-instructions on the iPhone during positional maneuvers and eye movement recoding.
American National Standard Institute (ANSI) Procedures for Testing Basic Vestibular Function. Not reported for predicate by manufacturer	Conformance by comparative performance testing of DDS 1.0.0 with predicate for position-ing and positional Nystagmus. ANSI S3.45-2009 (2014)	Substantially equivalent
Conformance to ISO, IEC, EN, CISPR, ASTM standards listed below. Not reported for predicate by manufacturer	Conformance to standards listed in table below.	Substantially equivalent

Testing: Testing showed the DizzyDoctor® System 1.0.0 to be in compliance with standards listed in the table. Quality System Management approaches were employed in the development of the DizzyDoctor® System 1.0.0 per 21CFR 820.

Biocompatibility testing was undertaken for Applied Parts of the VRG that may come in contact with a health professional or patient during testing. The DizzyDoctor® System 1.0.0 complied with the following recognized standards, as listed in the table: ISO10993-1: 2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process; ISO10993-5:2009, Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity ISO10993-10:2010; Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization. Additional durability testing of the VRG labels showed them to be resistant to abrasion and peel.

Software verification and validation was undertaken, and documents were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device." The software for this device was considered as a "moderate" level of concern, since a failures or latent design flaws in the software could lead to incorrect or delayed information that could result in non-serious injury of the patient. The device provides no diagnosis, and is one of a battery of tests that are currently used by physicians for vertiginous patients.

Usability/human factors (engineering) testing was performed in three studies. In Study 1, testing of the 30 unique user interface parameters for the DizzyDoctor® System 1.0.0 was performed in 10 subjects who were vertiginous and 10 who were non-vertiginous users. The results revealed that subjects completed the interface tasks competently. Even though two subjects were observed to have difficulty accomplishing a task at a particular interface, they were able to self-correct and complete the set-up, self-test and after-test activities completely and accurately. In Study 2, methodology similar to that in Study 1 was adopted, and this study extended to two audiologists' evaluations of in-use eye movement recordings and nystagmographs from the DizzyDoctor® System and from the predicate device. The results indicated that

the audiologists agreed 100% of the time with respect to the presence or absence of pathological nystagmus in the video recordings from the subject and predicate devices. Study 3 was performed in five subjects using similar methodology as in Studies 1 and 2, but aimed at determining whether changes for a software revision might interfere with functions of the user interface. The results indicated that all subjects accomplished the operational tasks. The software revision used in Study 3 was adopted as the production version of the DDS software (i.e., iOS App and Website/Web portal).

Performance, biocompatibility, electrical safety and electromagnetic compatibility (EMC) testing was undertaken on the DizzyDoctor® System 1.0.0, as itemized in the table below, in accordance with the requirements of the design control regulations and established quality assurance procedures. The device passed all testing and conformance standards listed, and represents a low level of residual risk.

Conclusion: The DizzyDoctor® System 1.0.0 Eye Movement Monitor is substantially equivalent to the predicate device.

#	Standard	Name	Date	FDA Recog-nition
1	IEC 60601-1:2005 +CORR 2006 +CORR 2:2007 + AM1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.	2012	**19-4**
2	IEC 60601-1-11	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	2015	**19-6**
3	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.	2014	**19-8**
4	CISPR 11:2009+A1:2010	Industrial, scientific and medical (ism) radio frequency equipment - radio disturbance characteristics - limits and methods of measurement.	2009	**No**
5	IEC 61000-4-2:2008	Electromagnetic compatibility - testing and measurement techniques - electrostatic discharge immunity test.	2008	**No**
6	IEC 61000-4-3:2006 A1:2007 + A2:2010	Electromagnetic compatibility - testing and measurement techniques -radiated radio frequency electromagnetic field immunity test.	2006	**No**
7	IEC 61000-4-4:2011	Electromagnetic compatibility - testing and measurement techniques - electrical fast transient / burst immunity.	2011	**No**
8	IEC 61000-4-5:2005	Electromagnetic compatibility - testing and measurement techniques - surge immunity test.	2005	**No**

9	IEC 61000-4-6:2003 + A1:2004 + A2:2006	Electromagnetic compatibility, testing and measurement techniques, conducted radio frequency electromagnetic field, immunity test.	2003	**No**
10	IEC 61000-4-8:2009	Electromagnetic compatibility - testing and measurement techniques - for power frequency magnetic field, immunity test.	2009	**No**
11	IEC 61000-4-11:2004	Electromagnetic compatibility - testing and measurement techniques - voltage dips, short interruptions and voltage variations immunity tests.	2004	**No**
12	ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process. (Biocompatibility)	2009	**2-156**
13	ISO 10993-5	Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.	2009	**2-153**
14	ISO 10993-10	Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization.	2010	**2-173**
15	ASTM D903	Standard Test Method for Peel or Stripping Strength of Adhesive Bonds.	2010	**5-42**
16	ASTM D1319	Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption, as modified Crock Test - Dry Rub & Wet Rub	2015	**No**
17	ASTM 5135	Standard Test Method for Analysis of Styrene by Capillary Gas Chromatography.	2016	**No**
18	IEC 61000-4-28	Electromagnetic compatibility (EMC) - Part 4-28: Testing and measurement techniques - Variation of power frequency, immunity test for equipment with input current not exceeding 16 A per phase.	2009	**No**
19	ISO 14971:2007	Medical devices - Application of risk management to medical devices.	2007	**5-40**
20	ISO 15223	BS EN ISO 15223-1: 2016. Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements, ISO 7000 Reg. No. 1641.	2016	**5-117**
21	EN 50419	BS EN 50419:2006. Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	2002	**No**
22	ANSI S3.45-2009 (Reaffirmed 2014)	American National Standard Procedures for Testing Basic Vestibular Function. (Dental/ENT): Positioning and Positional Nystagmus.	2014	**4-185**

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