

510(k) Summary
Nystagram™ Video Nystagmography System

APR 26 2013

Date Prepared: January 24, 2013

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Proprietary Name: Nystagram™ Video Nystagmography System

Common/Usual Name: Video Nystagmograph, VNG

Classification Name: Nystagmograph, 21 CFR 882.1460, Class II, Product Code GWN

Establishment Registration Number: 3008612563

Description:

The Nystagram™ is a device that views, records and measures both vertical and horizontal eye movements for support of identification of balance disorders. The results of the video nystagmograph (VNG) tests are combined with other clinical information to allow qualified medical personnel to determine the health of a patient's vestibular function system. The Nystagram™ system consists of a goggles system with a video camera and accelerometers to record eye movements and head position, computer monitors and other hardware and software to control the operation of the patient stimulus and the test administration functions. The system software is used for nystagmus analysis during oculomotor mobility, positional nystagmus, and caloric examinations. The results are presented in visual diagrams for clinical review.

Indications for Use:

The Nystagram™ is a video nystagmograph intended to view, record, and measure eye movements in support of identification of balance disorders. The device is intended for use only by qualified, trained medical personnel to aid in diagnostic recommendations. This device does not provide any medical diagnosis and is intended to be part of a larger balance assessment battery.

Substantial Equivalence:

The Nystagram™ Video Nystagmograph System is substantially equivalent to most commercially available VNG systems in the market. Specifically the Nystagram™ is substantially equivalent to the following predicate devices:

- BalanceBack VNG device (K042529)
- GN Otometrics ICS Chartr ENG/VNG System (K991497)
- Interacoustics 2D-VOG System (K072254)

All four devices have the same intended use and use similar technology and components. All patient preparation and test protocols are standard for all four devices.

Technological Characteristics:

Technically from a design and mechanism of action standpoint, the Nystagram™ is substantially equivalent to the predicate devices. They are all designed to record, view, and measure nystagmus in support of identification of balance disorders. The Nystagram and the predicate devices use similar technologies and components. Video cameras mounted to goggles record nystagmus. Infrared (IR) illumination of the eye area aids the cameras. Computer hardware and software detect and measure nystagmus during oculomotor mobility, positional nystagmus, and caloric examinations.

All patient preparation and test protocols are standard for the Nystagram™ and the predicate devices. The Nystagram™ and the predicate devices are designed for safety of the patient as well as the test administrator. All systems used IEC 60601 or variants to analyze safety.

Performance Bench Testing:

Tests of hardware and software have been performed to verify system specifications. Test plans were developed to ensure the product met all the specified requirements. The device conforms to the following standards:

- IEC 60601-1-1 (2000)
- IEC 60601-1 (2005)
- IEC 60601-1-2 (2007)
- ANSI S3.45(2009)

In addition, a comparative evaluation was conducted between the Nystagram™ and the GN Otometrics ICS Chartr VNG/ENG (Predicate Device) for the purpose of establishing clinical equivalency. Five (5) subjects' response to stimuli was measured and the resulting nystagmus or lack of nystagmus was recorded using the Predicate Device by an independent Audiologist located in Sugarland, Texas and the Nystagram™ by an independent Audiologist located in The Woodlands, Texas. The two testing sessions were within a 24 hour time period. The test battery included evaluation of Oculomotor function, Positional, Positioning and Spontaneous Nystagmus.

For the Oculomotor tests (Saccades, gaze and optokinetic), data were analyzed regarding symmetry and smoothness of eye movements and presence of nystagmus. Resultant tracings were clinically evaluated and judged to be:

- “Normal” for symmetrical eye movement without cog-wheeling or clinically significant nystagmus, OR
- “Abnormal” for all other findings

For the Positional tests without visual fixation (Supine, Head Right and Head Left), data were analyzed regarding the presence of clinically significant nystagmus. If so, the direction of the nystagmus was noted. Resultant tracings were clinically evaluated and judged to be:

- “Positive” if clinically significant nystagmus was present, OR
- “Negative” if no clinically significant nystagmus was present

For the Positioning Tests (Dix-Hallpike) and Spontaneous Nystagmus Tests, data were analyzed regarding the presence of clinically significant nystagmus. If so, the direction of the nystagmus was noted. Resultant tracings were clinically evaluated and judged to be:

- “Positive” if clinically significant nystagmus was present, OR
- “Negative” if no clinically significant nystagmus was present

The data collected from the Nystagram™ and Predicate Device were compared regarding the clinical findings of “Normal/Abnormal” or “Positive/Negative” for each test and subject. Equivalency between devices was demonstrated when interpretations of the data by each audiologist matched for each test and subject.

Test results verified that the devices are equivalent in their ability to capture eye motion, administer VNG test protocols and document Nystagmus for analysis by the clinician.

Conclusion:

Based upon the extensive testing conducted and the comparison to the predicate devices, it is the conclusion of Ototronix that the Nystagram™ is substantially equivalent to the predicate devices already on the market cleared by the 510(k) review process and presents no new concerns about safety or effectiveness.



April 26, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ototronix, LLC
c/o Bernard Horwath
4486 Timberline Ct
St. Paul, MN 55127

Re: K130201

Trade/Device Name: Nystagram Video Nystagmography System
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: January 24, 2013
Received: January 28, 2013

Dear Mr. Horwath:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket-Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Eric A. Mann -S

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

K130201

510(k) Number (if known): K130201

Nystagram™ Video Nystagmography System :

Indications for Use:

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~~This device does not provide any medical diagnosis and is intended to be part of a larger balance assessment battery.~~

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of Office of Device Evaluation (ODE)

Cherish R. Giusto-S
2013.04.19 14:40:36 -04'00'

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

510(k) Number K130201