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## 510(k) Summary

**Submitted by:**

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**Contact:**

Prof. Dr. rer. nat. Burkhard Fischer

**Trade Name:**

ExpressEye

**Common Name:**

Eye Movement Recorder

**Classification:**

Class II, 21 CFR 882.1460, Nystagmograph

**Device Description:**

ExpressEye measures horizontal eye movements and analyses the fixation quality, direction and reaction time of fast eye movements. The device consists of a head band, which carries light sources for visual stimuli, an amplifier, and infrared light emitting/receiving elements. A hand held processor controls the stimuli and analyses the eye movement signals. Optional the user can transfer the data to a personal computer.

**Intended Use:**

ExpressEye is used to measure the saccadic movements of the eye and classify a subject's performance in different tasks as normal or abnormal. Subjects are patients above the age of 6 years with suspicion of problems in dynamic vision and/or optomotor control.

**Substantial Equivalence:**

The ExpressEye is substantially equivalent to the House Infrared/Video Electronystagmograph System by Eye Dynamics, Inc. Both devices measure the movements of the eye by infrared light corneal reflection. Both instruments allow to display fast and slow eye movements. While ExpressEye analyses fast eye movements (saccades) the Nystagmograph permits viewing of the eyes and recording on video tape. Most technical details such as infrared illumination are the same. ExpressEye additionally generates visual target stimuli and provides appropriate analysis.

Summary of comparison with the predicate Device:

Item	ExpressEye	House IR/Video
Intended use	(Identical, with additional data analysis in ExpressEye)	
Sensor	video camera	phototransistors
Light source	infrared LEDs Peak Wavelength = 940 nm	infrared LEDs Peak Wavelength = 950 nm
Headmounting	plastic head band	eye goggles
Target projector	mini Lasers with low energy (Class II)	not present

Summary and conclusion of technical tests:

Laser:

The device meets the performance standard 21 CFR Part 1040 (light emitting products) part 10 (laser products). The lasers are classified as Laser Class 2. The use of the lasers to project visual targets on a surface in front of the test person is safe, because the power of the lasers is only 0.2 milliwatts, 5 times less than permitted for a laser class 2 device.

Infrared light:

the infrared light used by the device has a spectral radiance and irradiance inside the Threshold Limit Value recommended by the American Conference of Governmental Industrial Hygienists.

Electromagnetic Interference:

The electromagnetic compatibility was measured by a laboratory approved by the U.S. FCC. They certified that the radiation is below the level allowed for class A. Therefore the following text appears in the device manual:

Warning - This is a Class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

The disturbance of the device by outside radiation found in the measurement is eliminated by added shielding.

Biocompatibility:

The materials of the head band are declared biocompatible and conformant to European and US regulations by the manufacturer of the head band.

The additional acquirement of variables from the eye movement traces does not affect the safety because it results in recommendations of training procedures, not in any kind of medication.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 12 1999

Dr. Burkhardt Fischer  
Optomotor Laboratories  
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Germany

Re: K992473  
Trade Name: ExpressEye  
Regulatory Class: II  
Product Code: GWN  
Dated: July 15, 1999  
Received: July 26, 1999

Dear Dr. Fischer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

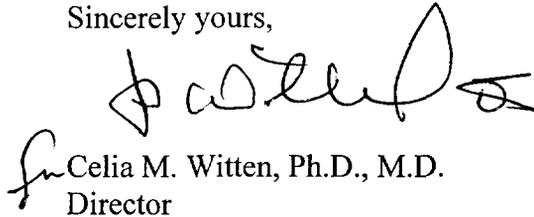
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Dr. Burkhard Fischer

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

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

Enclosure

