DIFRA

SEP 18 2007
ISO 9001-2000

510(k) Summary

Submitter Information:

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Registration Number:	9710334
Contact Person:	Guido Pagnacco, Ph.D., US Agent
Summary Date:	July 5, 2007

Device Information:

Common/Usual Name:	Nystagmographer (video or electrode)
Trade/Proprietary Name:	EyeTracker, IDEAS
Regulation Number:	882.1460
Regulation Name:	Nystagmograph
Regulatory Class:	II
Product Code:	GWN

K070670

(Premarket Notification [510(k)] Number)

DIFRA S.A./N.V.

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Substantial Equivalency:

The device is substantially equivalent to:

- the CHARTR ENG/VNG Diagnostic System (K991497) marketed by ICS Medical Corporation
- the ENGPLUS (K010059) marketed by Western System Research, Inc.
- the VISUAL EYES (K964325) marketed by Micromedical Technologies, Inc.

For its ability to record torsional movements, the device is substantially equivalent to:

- the ULMER (VNG) VIDEO NYSTAGMOGRAPH (K982103) marketed by Synapsys, Inc.
- the I-PORTAL, also known as I-PORTAL VNG, part of the NEURO-OTOLOGIC TEST CENTER (K781268) marketed by Neuro Kinetics, Inc.

Description of the device:

The device is a PC-based system for measuring, recording and displaying the eye movements. Its components include video goggles or surface electrodes to record the eye movements, a PC interface to acquire the data, a series of software modules to display and analyze the data and various stimulation devices.

Intended use:

The device is intended to measure, record and display the movements of the eyeballs during their involuntary movements (nystagmus) and while testing the patient's vestibular function.
The device is for prescription use only and it is intended for use by qualified medical personnel trained in the use of nystagmographs. This device provides no diagnoses nor does it provide diagnostic recommendations.

Technological Characteristics:

Device specifications	EYETRACKER / IDEAS	CHARTR ENG/VNG	ENGPLUS	VISUAL EYES	ULMER (VNG) VIDEO NYSTAGMOGRAPH	I-PORTAL, (NEURO-OTOLOGIC TEST CENTER)
Safety compliance	EN 60601-1	EN 60601-1	EN 60601-1	EN 60601-1	EN 60601-1	EN 60601-1-2
Type	Video / Electrode based system	Video / Electrode based system	Electrode based system	Video based system	Video based system	Video based system
Construction type	PC-based system with built-in hardware and peripherals	PC-based system with built-in hardware and peripherals	PC-based system with external hardware platform and peripherals	PC-based system with external hardware platform and peripherals	PC-based system with built-in hardware and peripherals	PC-based system with external hardware platform and peripherals
Power source	Mains	Mains	Mains	Mains	Mains	IEEE firewire cable
Computer interface	Integrated in computer	Integrated in computer	Serial or USB connection	USB connection	Integrated in computer	IEEE firewire cable

Safety:

The device is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1:1990 Medical Electrical Equipment. Part 1: General requirements for safety
- EN 60601-1-2:2001 Medical Electrical Equipment. Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

The device is designed, developed and manufactured according to the following standards:

- ISO 9001:2000 Quality Management Systems-Requirements
- ISO13485:2003 Quality management Systems – Requirements

The device satisfies all the requirements of the European Community Medical Device Directive MDD 93/42/EEC and bears the CE mark.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 2007

S.A. Instrumentation DIFRA
% Vestibular Technologies, LLC
Guido Pagnacco, Ph.D.
205 Co. Rd., 128A
Suite 200
Cheyenne, WY 82007

Re: K070670
Trade/Device Name: EyeTracker, IDEAS
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: July 5, 2007
Received: July 6, 2007

Dear Dr. Pagnacco:

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070670

Device Name: EyeTracker, IDEAS

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhoan
K070670

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

510(k) Number K070670