K061791

JUL 11 2006

510(k) Summary of Safety and Effectiveness

Submitter

Name and address:	GN Otometrics A/S Dybendalsvaenget 2 DK-2630 Taastrup Denmark
Phone:	+45 7211 1555
Fax:	+45 7211 1548
Contact person:	Per Pape Thomsen

Summary prepared: January 30, 2006

Device name

Common/Usual name:	Vestibular Testing System
Trade/Proprietary name:	Focus VNG/ENG type 1068
Classification name:	Nystagmograph

Predicate device

Focus VNG/ENG is similar to the product ICS Medical CHARTR ENG/VNG Diagnostic System (K991497) but differs in three ways: external hardware platform with USB interface, software and video goggles.

Description

The Focus VNG/ENG is a PC-based system, which consist of software modules for installation on a PC, an isolation transformer, a hardware platform, a mains adapter, stimulation devices and recording devices.

The stimulation and recording devices are connected to the hardware platform, which is connected to the PC via a USB cable – no hardware installation inside the PC is required.

Indications for Use

The Focus VNG/ENG is a nystagmograph that is intended to measure, record, and display involuntary movements (nystagmus) of the eyeball.

Technological Characteristics

Device Specifications	**Focus VNG/ENG**	**CHARTR ENG/VNG**
Safety compliance	EN 60601-1	EN 60601-1
Construction type	PC-based system with external hardware platform and peripherals	PC-based system with built-in hardware and peripherals
Power source	Mains	Mains
Computer interface	USB cable connection	Integrated in computer

Safety

Focus VNG/ENG is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1:1990, UL 60601-1:2003, CAN/CSA-C22.2 NO 601.1-90:1990 Medical Electrical Equipment. Part 1: General requirements for safety
- EN 60601-1-1:2001: Medical Electrical Equipment. Part 1: Generel requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems
- EN 60601-1-2:2001 Medical Electrical Equipment. Part 1-2: Generel requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-2-40:1998 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment

Focus VNG/ENG is designed, developed and manufactured according to the following standards:

- ISO 9001:2000 Quality Management Systems – Requirements
- ISO13485:2003 Quality management systems - Requirements for regulatory purposes

Effectiveness

The Focus VNG/ENG is a nystagmograph for replacement of an existing product of a technology type that is available and accepted in the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GN Otometrics A/S
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087

JUL 11 2006

Re: K061791
Trade/Device Name: Focus VNG/ENG type 1068
Regulation Number: 882.1460
Regulation Name: Nystagmograph
Regulation Class: II
Product Code: GWN
Dated: June 23, 2006
Received: June 26, 2006

Dear Mr. Lehtonen:

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

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): K061791

Device Name: Focus VNG/ENG type 1068

Indications For Use:

The Focus VNG/ENG is a nystagmograph that is intended to measure, record, and display involuntary movements (nystagmus) of the eyeball.

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)

Barbara Krieger

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

510(k) Number K061791