K072254

510(K) SUMMAREY OF SAFETY AND EFFECTIVENESS

2D-VOG$_{fw}$ System

SUBMITTER INFORMATION

A	Company Name:	Interacoustics A/S
B	Company Address:	Drejervaenget 8 Assens, DK-5610, Denmark
C	Company Phone:	+45 6371 3555
	Company Fax:	+45 6371 3522
D	Contact Person:	Hanne Nielsen Quality Manager Interacoustics A/S
E	Date Summary Prepared:	30/07/2007

FEB - 5 2008

DEVICE IDENTIFICATION

A	Generic Device Name:	Nystagmograph
B	Trade/proprietary Name:	2D-VOG$_{fw}$ System 2D-VOG$_{fw}$ goggle VN415m VN415b VO425m VO425b
C	Classification:	Class II
D	Product Code:	GWN

SUBSTANTIAL EQUIVALENCE

Predicate Device	**Manufacture**	**510(k) No.**	**Date Cleared**
2D VOG-Videooculography	SensoMotoric Instruments	K972243	09/10/1997

DEVICE DESCRIPTION

This system consists of a PC or Laptop (requirements specified), a 2D-VOG$_{fw}$ Goggle and a software platform that by licensing enables different levels of functionality recognized as the VN415m, VN415b, VO425m, VO425b products.

The 2D-VOG$_{fw}$ Goggles component comprises housing and one or two cameras depending on the license obtained for this system. Cameras number two can be added to the 2D-VOG$_{fw}$ Goggles afterwards with the goggles by upgrading the product license. The 2D-VOG$_{fw}$ Goggles may be added to other products within the 2D-VOG$_{fw}$ System in the future.

The 2D-VOG$_{fw}$ Goggle is connected to the PC via a standard Firewire connection.

Optionally a rotating chair can be added to the 2D-VOG$_{fw}$ System. The chair shall meet our specifications developed for compliance with the 2D-VOG$_{fw}$ System.

Functionalities of the products may be controlled by a remote control and/or a foot switch. These controls are connected to the PC via a wireless connection by means of a USB wireless receiver/transmitter.

Test results and reports are formatted and printed by the 2D-VOG$_{fw}$ System software. A database containing test results and other patient information can be located and shared on the PC.

INTENDED USE

VN415m, VN415b, VO425m, VO425b systems provide information to assist in the Oculographic evaluation, diagnosis and documentation of vestibular disorders.

Nystagmus of the eye is recorded by use of goggle mounted cameras. These images are measured, recorded, displayed and stored in the software. This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the 2D-VOG$_{fw}$ System and the predicate device has been performed. The results of this comparison demonstrate that the 2D-VOG$_{fw}$ System is equivalent to the marketed predicate device.

PERFORMANCE DATA

The performance data indicated that the 2D-VOG$_{fw}$ System meets all specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2008

Interacoustics A/S
% Mr. Daniel Eggan
Interacoustics USA
7625 Golden Triangle Drive
Eden Prairie, MN 55344

Re: K072254
Trade/Device Name: VN415m, VN415b, VO425m, VO425b, 2D-VOG$_{fw}$ Goggles, 2D-VOG$_{fw}$ System
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: January 16, 2008
Received: January 17, 2008

Dear Mr. Eggan:

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 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 Statement

Applicant: Interacoustics A/S

510(k) Number (if known): _____

Device Name: VN415m, VN415b, VO425m, VO425b

Indications For Use:

VN415m, VN415b, VO425m, VO425b systems provide information to assist in the Oculographic evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by use of goggle mounted cameras. These images are measured, recorded, displayed and stored in the software. This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

(Per 21 CFR 801.109)

510(k) Number K072254