K972243

SEP 10 1997

510(k) Summary
SensoMotoric Instruments 2D VOG -- Video-Oculography®

Sponsor:

SensoMotoric Instruments, GmbH ("SMI")
Potsdamer Str. 18a
14513 Teltow
GERMANY
011-49-3328-430-300 (telephone)
Contact: Annikki Persson, Product Manager for Medical Applications

Trade Name: 2D VOG - Video-Oculography®

Common Name: Nystagmograph

Classification: Class II, 21 C.F.R. § 882.1460, Nystagmograph

Device Description: The 2D VOG measures horizontal and vertical eye movements and analyzes the eye movements for nystagmus beats and velocity. The results are visually displayed in different diagrams and are stored in a patient manager together with patient data. The device is intended to provide information for use by the health care professional, in conjunction with other clinically relevant information, in the diagnosis of vestibular disorders.

The 2D VOG consists of a video camera mounted in a mask to record eye movements, an image processing board to digitize and analyze eye movement data, a video-overlay board and PC for real time display of eye movements, and software to analyze and display eye movement data. The system has a patient database for storage of patient data and results.

The 2D VOG system software is used for nystagmus analysis during spontaneous nystagmus, caloric, smooth pursuit, optokinetic, rotation, positional, and saccadic examinations.

Substantial Equivalence Determination:

The 2D VOG is substantially equivalent the House Infrared/Video Electronystagmograph System marketed by Eye Dynamics, Inc. Both devices use similar technology, including PC and computer monitor, masks mounted with video cameras, and software for performing spontaneous, caloric, positional, rotational, optokinetic, saccadic, and smooth pursuit examinations. The devices utilize the same sampling rate and illumination wavelength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Annikki Persson
Product Manager Medical Applications
SensoMotoric Instruments, GmbH
Potsdamer Straβe 18a
D - 14513 Teltow
GERMANY 14513

Re: K972243
Trade Name: 2D VOG - Video-Oculography
Regulatory Class: II
Product Code: 84GWN
Dated: June 11, 1997
Received: June 16, 1997

Dear Ms. Persson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972243

Device Name: 2D VOG -- Video-Oculography

Indications For Use:

The 2D VOG -- Video-Oculography system provides information to assist in the diagnosis of vestibular disorders by measuring, recording, storing, displaying, and analyzing nystagmus of the eye.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972243

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)