K972631

SEP 22 1997

510(k) SUMMARY

Submitted by:	ICS MEDICAL CORPORATION 2227 Hammond Drive Schaumburg, IL 60173-3860
Telephone:	(847)-397-2150
Fax:	(847)-397-0666
Contact Person:	Delmar F. Bloem, President
Date Summary Prepared:	July 3, 1997
Trade Name of Device:	ICS VEMR™ Eye Movement Recorder
Common Name:	IR/Video Eye Movement Viewer/Recorder
Classification Name:	Nystagmograph (CFR882.1460)

Substantial Equivalence: The ICS VEMR™ Eye Movement Recorder is substantially equivalent to the one used in the House InfraRed/Video Electronystagmograph System for which the company received their 510(k) approval except that our unit is a stand-alone device that only permits viewing of the eyes and recording their movements on video tape. Our device does not perfom any analyses or measurements of the images.

Description of the Device:

The VEMR™ Eye Movement Recorder is used to observe or record eye movements on a video monitor or video recording tape respectively. This device consists of: patient eye goggles, a video image splitter/power-supply, a video tape cassette recorder (VCR) video monitor console, and a remote control accessory. There is also a built-in microphone in the eye goggles to provide simultaneous voice recording's on a video recording tape.

The patient eye goggles are an opaque, facially worn device fitted with tiny video cameras, infrared light emitting diodes (LED's), and a microphone. The diodes

illuminate the eyes for video cameras that produce video signals. These signals are processed by the image processor that essentially allows for simultaneous viewing the video images of both eyes on the video screen. The microphone allows for recording of voices to help document events recorded on video tape. The remote control accessory provides remote control of the various functions (e.g. play, record etc.) on the VCR/video monitor console.

Intended Use:

This device is used to record and visually display movements of the eyes including nystagmus.

Summary of Technological Similarities and Differences to the Predicate Device:

Item	ICS VEMR	Jedmed House Ir/video Vue Goggle System
Goggles fitted with IR sensitive video cameras.	Yes	Yes
IR Source	IR LEDs Peak Wavelength (λ) = 940 nanometers	IR LEDs Peak Wavelength (λ) = 940 nanometers
Light tight eyegoggles	Yes	Yes
Material in contact with face	Soft PVC plastic	Foam material (unknown composition)
Image splitter/power supply interface	Yes	Yes
Built-in microphone	Yes	No
Intended use	Identical for both units	
Video recording capability	Yes (built-in VCR)	Yes (need optional VCR)
Video-goggle		

interface	Both units have an interface that allows for display of both eyes on video monitor and provides the power for the video cameras and the LEDs.

Summary of Non-Clinical Tests:

The plastic portion of the goggle material that is in contact with the skin was subjected to:

1. MEM Elution Cytotoxicity Test (performed according to GLP regulations) - The test article **does meet** the requirements of this test.

2. Primary Skin Irritation Test on Rabbits (performed according to GLP regulations) - Findings: " ...the test article, Sellstrom Gold PVC Goggle; lot Identification: May 7, 1997, **is not considered an irritant.**

The ICS VEMR™, Video Eye Movement Recorder was subjected to a battery of EMI (Electromagnetic interference) and other electrical tests.

The system **passed** the requirements of the following standard tests:

CISPR 11 B (EN55011) Conducted Emissions
CISPR 11 A (EN55011) Radiated Emissions
Military Standard 461 RE 101 Magnetic Emissions
ENV 50140 (IEC 1000-4-3) Radiated Susceptibility Test
EN 61000-4-2 Electrostatic Discharge Test
EN 610 00-4-4 Transient Susceptibility Test
EN 61000-4-5 Surge Immunity Test

The VEMR unit, based on above findings, will require the following labeling in the VEMR instruction 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.

Tests on the VEMR™ performed at ICS Medical demonstrated that this units meets the requirements of UL-544/42 (dielectric withstand) and UL-544/46 (leakage current).

Finally, radiometric measurements of the infrared emitting diodes in the VEMR Goggles were made in order to determine whether the spectral radiance and irradiance is within the Threshold Limit Values (TLV's) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH). We determined that the maximum irradiance of the infrared diodes used in the VEMR goggles is approximately 1/270 of the recommended ACGIH TLV of 10 milliwatts/cm^2 .

Likewise the maximum radiance emitted by the VEMR infrared diodes was shown to be approximately 1/1700 of the recommended ACGIH TLV of TLV of 35.3 watts/cm^2 (sr).

Based on the above radiometric findings the infrared energy emitted by the small diodes in the VEMR Goggles is well below the recommended ACGIH TLV guidelines thus posing no threat to the patient's eyes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1997

Mr. Delmar F. Bloem
ICS Medical Corporation
2227 Hammond Drive
Schaumburg, Illinois 60173-3860

Re: K972631
Trade Name: ICS Medical VEMR Video Eye Movement Recorder
Regulatory Class: II
Product Code: 84GWN
Dated: July 11, 1997
Received: July 14, 1997

Dear Mr. Bloem:

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): K972631

Device Name: ICS Medical VEMR

Indications For Use:

This device is used to record and visually display movements of the eyes including nystagmus.

(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 K972631

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)