DEC 1 0 2001

510(k) SUMMARY K013060

Submitted by: ICS MEDICAL CORPORATION
125 Commerce Drive
Schaumburg, IL 60173-5329

Telephone: (847)-534-2150

FAX: (847)-534-2151

Contact Person: Robert M. Simenson, Executive Vice President

Date Summary Prepared: September 7, 2001

Trade Name of Device: ICS Medical Model VG-30 Video Goggle

Common Name: Video goggle

Classification Name: Accessory to: Nystagmograph, Class II, 21 CFR 882.146

Description of Device: The ICS Medical Model VG-30 Video Goggle consists of two small video cameras mounted in a custom housing to be worn on the face of the patient to view the patients eyes. The goggles use infrared (IR) Illumination to allow the eyes to be viewed in total darkness, a feature produced by a cover that can be installed on the front of the goggle housing.

Intended Use: This device is intended to provide video signals of patient's eyes thus making it possible to observe, record, and measure eye movements during testing of vestibular function.

Substantial Equivalence: The Model VG-30 Video Goggles are substantially equivalent to the Model VG-10 Goggles cleared in 510(k): K991497.

Comparison of Similarities and Differences of Our New Medical Device to the Predicate Device:

	ICS Video Goggle (510K : K991497)	ICS Medical Model VG-30 Goggle
Housing Material	ABS Plastic	ABS Plastic
Face Cushion Material	Neoprene Rubber	Polyvinyl Chloride
Number of Light Emitting Diodes (LED's)	7 per eye (Total: 14)	Identical
Mirror Adjustment Capability to Center the Image	Yes	Yes
Horizontal Image Adjustment Accomplished by Means of Mirror Adjustment	Yes	Yes

Vertical Image Adjustment Accomplished by Adjusting Cameras	Yes	Yes
Mirror Material	Polycarbonate plastic	Identical
Strap Material	Neoprene Rubber	Identical
Video Camera Adjustment Capability	Yes	Yes
Friction Fit Light Occluding Cover	Yes	Identical
Weight	Approximately 21 oz.	Approximately 18.5 oz.

Please note that with the exception of the face cushion material both these goggles are virtually identical in design and materials.

The Model VG-30 Video Goggle is designed to meet the same safety standards as the predicate device, i.e. ICS Medical Model VG-10 Video Goggles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2001

Robert M. Simenson
Executive Vice President
ICS Medical Corporation
125 Commerce Drive
Schaumburg, Illinois 60173-5329

Re: K013060
Trade Name: ICS Medical Model VG-30 Video Goggle
Regulation Number: 882.1460
Regulation Name: Nystagmograph
Regulatory Class: II
Product Code: GWN
Dated: September 7, 2001
Received: September 11, 2001

Dear Mr. Simenson:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 013060

Device Name: ICS Medical Model VG - 30 Video Goggles

Indications For Use:

The ICS Medical Model VG-30 Video Goggles are intended to provide video signals of patient's eyes thus making it possible to observe, record, and measure eye movements during testing of vestibular function.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Susan Walker

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

510(k) Number K013060