JUL 28 1999

K 991497

510(k) SUMMARY

Submitted by: ICS MEDICAL CORPORATION
2227 Hammond Drive
Schaumburg, IL 60173-3860

Telephone: (847)-397-2150

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Contact Person: Delmar F. Bloem, President

Date Summary Prepared: July 23, 1999

Trade Name of Device: ICS Medical CHARTR® ENG/VNG Diagnostic System

Common Name: Nystagmograph

Classification Name: Nystagmograph, Class II, 21 CFR 882.146

Substantial Equivalence: The CHARTR® ENG/VNG Diagnostic System is substantially equivalent to the 2D VOG-VIDEO- OCULOGRAPHY device marketed by SensoMotric Instruments, GmbH ("SMI") and the CHARTR®ENG SYSTEM marketed by ICS Medical Corporation.

Description of Device:
The CHARTR® ENG/VNG Diagnostic System is a computer based medical device consisting of a Computer utilizing the Pentium III processor, Windows 98 Operating System, Computer Monitor, two Display Monitors for viewing eye movements and utilizes the following accessories: Light Bar, Video Goggles, External Isolation Transformer, Video Distribution Amplifier, Caloric Stimulator, Color Printer, Patient Electrodes, and Interconnection Cables.

Intended Use: This Device is used to observe, record, and measure eye movements in patients during testing of vestibular function.

Y2K Compliance: This system is Y2K compliant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 1999

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

Re: K991497
Trade Name: ICS Medical CHARTR® ENG/VNG Diagnostic System
Regulatory Class: II
Product Code: GWN
Dated: April 27, 1999
Received: April 29, 1999

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4595. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K991497

Device Name: ICS Medical CHARTR ENG/VNG Diagnostic System

Indications For Use:

This device is used to observe, record and measure eye movements in patients 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991497

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)