DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1998

Ms. Vera Buffaloe
Medical Device Consultant
Acting Director, Regulatory Affairs
Synapsys, Inc.
1400 Main Street
Louisville, Colorado 80027

Re: K982103
Trade Name: Ulmer (VNG) Video Nystagmograph
Regulatory Class: II
Product Code: GWN
Dated: June 12, 1998
Received: June 15, 1998

Dear Ms. Buffaloe:

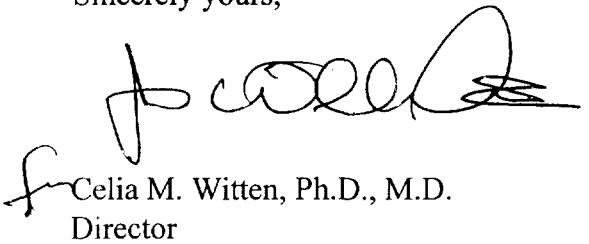
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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/dsma/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

Indications for Use

510 (k) Number (if known): 982103

Device Name: Synapsys Ulmer Video Nystagmograph

Indications for Use:

The Ulmer Video Nystagmograph System is intended for use by the physician as an aid for the detection and diagnosis of vestibular disorders. The Ulmer VNG detects and displays eye position and movement in response to a number of vestibular stimulations, i.e. saccadic test, smooth pursuit, optokinetic nystagmus, caloric tests, and kinetic vestibular tests. The Ulmer VNG records and analyzes the bilateral, monocular, horizontal, and vertical aspects of eye position and movement.

This device is intended to be used in a doctor's office or health care facility to obtain recorded data of nystagmus by directly observing eye motion by video-cameras. The resulting recorded data is evaluated by a trained physician and considered along with other relevant data in diagnosing vestibular disorders.

(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 K982103

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)