

AUG - 3 2001

K 011397

## **Section 2 - Summary of Safety and Effectiveness**

### **Stellate Sensa**

The Stellate Sensa (predicate device) is a software only product. It runs on a personal computer and identifies spike and seizure events. These events are then reviewed, possibly deleted, and interpreted by the user.

Neither the computer nor the software control the delivery of energy, the administration of parenteral drugs, or another form of life sustaining function to the patient.

No diagnostic or effectiveness claims are made.

### **Persyst Reveal**

The Persyst Reveal is a software only product. It runs on a personal computer and requires no specialized hardware. It identifies spike and seizure events. These events are then reviewed, possibly deleted, and interpreted by the user. The digitized EEG input is read from a file on the personal computer (or available across the network).

Neither the computer nor the software control the delivery of energy, the administration of parenteral drugs, or another form of life sustaining function to the patient.

No diagnostic or effectiveness claims are made.



AUG - 3 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Scott B. Wilson  
President  
Persyst Development Corporation  
316 Skyline Drive  
Prescott, Arizona 86303

Re: K011397  
Trade/Device Name: Persyst Reveal  
Regulation Number: 882.1420  
Regulatory Class: Class I  
Product Code: GWS  
Dated: May 2, 2001  
Received: May 7, 2001

Dear Mr. Wilson:

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.

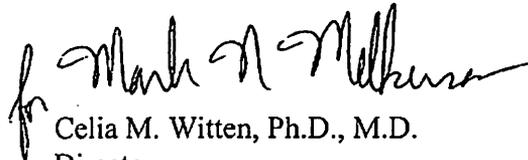
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Scott B. Wilson

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) 594-4659. 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 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C".

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): 011397

Device Name: Persyt Reveal (previously Persyst SpikeDetector)

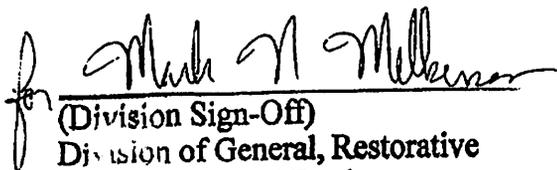
Indications for Use:

This software is intended for use by a trained EEG technician or neurologist.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number     K011397    

(Optional Format 3-10-98)