



March 25, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Stellate Systems
c/o Mr. George Papagiannis
345 Victoria Avenue, Suite 505
Westmount, Quebec
Canada H3Z 2N2

Re: K960273

Trade/Device Name: Harmonie and Sensa EEG Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMB, OLT
Dated (Date on orig SE ltr): January 17, 1996
Received (Date on orig SE ltr): January 19, 1996

Dear Mr. Papagiannis:

This letter corrects our substantially equivalent letter of April 4, 1996.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device: HARMONIE and Sensa Software

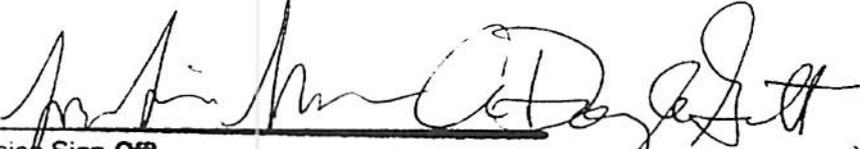
510(k) Number: K960273

Indications For Use

HARMONIE™ and Sensa™ is a set of software programs which represent an improved implementation of Stellite Systems' RHYTHM and MONITOR software. The software remains consistent with its original design objectives:

- to assist in the scientific analysis of the electroencephalogram (EEG) in the field of human and animal neurophysiology.
- to offer digital EEG recording by means of a personal computer and PC-based data acquisition boards.
- to assist in the selection of EEG sections of potential interest and offer a variety of display, playback and review capabilities.
- to complement the conventional continuous EEG recording, not replace it.

The software does not make any judgment of normality or abnormality of the displayed EEG or the results of an analysis. It is not intended for extended EEG monitoring used in critical care or intra-operative settings. In no way is the software or its function represented as being in and of itself diagnostic.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices K960273
510(k) Number K960273

Acting Group Leader,
PNDG