AUG 6 1998

K980477

EXHIBIT 2

SAM Technology, Inc.
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San Francisco CA 94105
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sam@eeg.com

Contact: Alan S. Gevins, President

July 28, 1998

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: IMAGE VUE EEG Software
   Classification Name: Electroencephalograph, OLX, Regulation # 882.1400
   Common/Usual Name: Electroencephalograph Software

2. **Equivalent legally marketed devices** This product has features which are similar in design and function to the K960071, Radionics Image Correlation System; K843598, Nicolet Biomedical Instruments Brain Function Mapping Option For Pathfinder; and K970951, The Grass Electroencephalograph Software .

3. **Indications for Use (intended use)** The software is intended for use by a qualified/trained EEG technologist or physician on both adult and pediatric subjects for the visualization of human brain function and structure by fusing a variety of EEG information with MRI images.

4. **Description of the Device:** The software imports digital EEG data (in a variety of formats) and MRI data and permits the fusing and viewing of both types of data. No direct intervention, treatment, or on-line monitoring of the patient is performed.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicate that the new device is as safe and effective as the predicate devices.

6. **Conclusion**
   After analyzing both bench and user testing data, it is the conclusion of SAM Technology, Inc. that the IMAGE VUE EEG software is as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sam Technology, Inc.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm and Associates
P.O. Box 7007
Deerfield, Illinois 60015

APR - 9 2012

Re: K980477
Trade/Device Name: Image Vue EEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX
Dated (Date on orig SE ltr): May 15, 1998
Received (Date on orig SE ltr): June 5, 1998

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of August 6, 1998.

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 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K980477

Device Name: IMAGE VUE EEG Software

Indications for Use:

The software is intended for use by a qualified/trained EEG technologist or physician on both adult and pediatric subjects for the visualization of human brain electrical activity by fusing a variety of EEG information with MRI images.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980477

Prescription Use √ OR Over the Counter Use _____
(Per 21 CFR 801.109)