Chatten Associates

1094 New Dehaven Avenue
West Conshohocken, PA 19428

www.chattenassociates.com
610 940-6040
fax 610 940-6068

K082629

JUL - 1 2009

5. 510(k) Summary

Submission Date: September 5, 2008

Submitted by: **Chatten Associates, Inc.**
1094 New Dehaven Avenue, Suite 200
West Conshohocken, PA 19428 U.S.A
Phone: 610-940-6040 FAX: 610-940-6068

Contact Person: John B. Chatten, President
Tel: (610) 940-6040
E-mail: jchatten@chattenassociates.com

Proprietary Name: S12X with ESAx Option

Common/Usual Name: Cortical Stimulator with Switching Unit

Product Classification:
Category: Electrode, Cortical (*based on Predicate Device Ojemann Cortical Stimulator #K924226*)
Regulation Number: 882.1310 (*based on Predicate Device Ojemann Cortical Stimulator #K924226*)
Product Code: GYC (*based on Predicate Device Ojemann Cortical Stimulator #K924226*)
Product Class: Class II

Substantial Equivalence to:
- **Ojemann Cortical Stimulator (K924226),** Radionics/Integra Lifesciences Corporation, Plainsboro, NJ
- **EMU128S, MODEL EX-NW128S (K040360),** Excel Tech, LTD (XLTEK), Oakville, ONT, Canada; now a division of Natus Medical, Inc., San Carlos, CA
- **EEG-1100A Switch Box (K073491),** Nihon Kohden America, Inc., Foothill Ranch, CA
- **S12 Cortical Stimulator,** marketed prior to May 28, 1976 and sold as a research device, Grass Instruments Inc., now Grass-Technologies, an Astro-Med, Inc. Product Group, West Warwick, RI

Intended Use:

The **S12X** Cortical Stimulator is intended for Intraoperative cortical stimulation mapping to aid in cortical resections in the vicinity of essential cortex. The device is intended for use only by medically trained and qualified personnel, within a hospital or medical environment. The **ESAx** option is intended for use with the S12X for facilitating the switching of the patient electrodes.

Device Description:

S12X Cortical Stimulator:

The S12X Stimulator supplies a bi-phasic, constant current electrical pulse sequence that is suitable for cortical stimulation. Currents can be applied to the surface of the cortex either with a Manual Probe or through a set of electrodes and the Electrode Switch Array (ESAx) option. Electrodes, either the Manual Probe or other grid and strip electrodes, are not considered part of the S12X.

The S12X is intended to replace the obsolete and discontinued S12 Stimulator in the product line of Grass Instruments, Inc. (now Grass-Technologies, an Astro-Med, Inc. Product Group), marketed prior to May 28, 1976 and sold as a research device thereafter. The essential functions of the S12 have been retained, but appropriate isolation and insulation features have been modified to meet modern regulatory requirements for use with human patients. In order to provide for applications and expansions of function compatible with modern medical data systems, hardware timing circuits have been replaced with an embedded controller whose crystal controlled counters replace the hardware timing functions, and the panel controls have been largely replaced with a touch screen graphical user interface (GUI).

The S12X device consists of an external medical grade power supply, the S12X Stimulator Unit, and the optional ESAx electrode selector adapter. The S12X front panel consists of hardware switches for controlling the "Stimulate" and "All Stop" functions, and a color LCD touch screen display with instrument-style controls for setting up the stimulation parameters, calibrating the device, viewing the stimulation log file contents, and for selecting electrodes for stimulation. User input is via a stylus (for touch panel use) or via a standard mouse. The optional ESAx unit connects to a multi-pin connector on the side panel of the S12X.

The S12X accumulates a log of stimulation events, their time-of-day, and their parameters. The log file can be easily transferred to a USB flash drive or equivalent for electronically filing or printing of the stimulation log.

No transient voltage can exceed 34 volts on the patient electrodes (limited by a Zener diode across the patient leads). Further, if after two pulses the internal voltage monitor detects pulse voltages greater than 30 volts, the pulse train will terminate.

No sustained direct current can pass through the patient leads since the output stimulus is entirely transformer coupled. The unit is powered by an external regulated 12 volt DC medical-grade supply powered by standard mains voltage of 120V or 250V AC, and meets U.S. and European regulatory standards: IEC 60601-1-1, and IEC 60601-1-2.

ESAx Electrode Switch Array:
The ESAx is an optional accessory to the S12X which facilitates rapid functional brain mapping during presurgical workups and during surgery. The ESAx is an array of optically coupled relays that can select electrodes from an electrode grid array when more than one electrode pair is in contact with the cerebral cortex, usually in the form of strips or grids. Note that the cortical electrode strips or grids are not part of the device, and they are purchased by the user from other vendors. The ESAx connects the desired electrode pair to the stimulator and simultaneously disconnects the corresponding EEG amplifier leads from the amplifier. The choice of electrodes to be stimulated is controlled from a touch screen display on the S12X.

The ESAx has no buttons or switches, and consists of multi pin connectors for connecting to the S12X and for connecting EEG electrode jack boxes and EEG amplifier unit(s). Note that the EEG jack boxes and the multi-channel EEG amplifiers which can connect to the ESAx are not part of the S12X device, and therefore are not part of this 510(k) submission.

Summary of Comparison to Predicate Devices:

The basic performance parameters and intended use of the S12X are essentially the same as the OCS-1 Ojemann Cortical Stimulator currently marketed and sold by Integra Lifesciences Corporation and authorized by 510(k) #K924226. The S12X is also equivalent to the predicate device in terms of safety, effectiveness, and performance.

The differences between the S12X and OCS-1 are the following:

- The Ojemann OCS-1 is battery powered with four 9V alkaline batteries, where the S12X uses a medical grade isolating power supply with a +12V DC output.

- The maximum available current of 10 milliamperes peak in the OCS-1 Ojemann Stimulator has been increased to 15 milliamperes in the S12X, for all pulse widths up to and including 1000 microseconds. At the largest pulse width of 2000 microseconds, the available current is still limited to 10 milliamperes in

order to stay within the 20 microcoulomb charge limit of the OCS-1 Ojemann stimulator. The current increase at shorter pulse widths was made available in the S12X because common stimulation practice when used at pulse widths of 300 microseconds often requires a maximum current of 15 milliamperes. The maximum available power output to the patient leads in the OCS-1 is 80 milliwatts. The maximum currents, voltages, pulse widths and frequencies of the S12X have been specified to limit the maximum power to the patient to 60 milliwatts.

- The OCS-1 Ojemann front panel has knobs and switches for controls, whereas the S12X uses a touch-screen for setting parameters. However, controls essential to safety, such as "Stimulate" and "All-Stop", are still controlled by hardware push-buttons and hard-wired logic.

- The S12X has an additional pulse shape feature, Alternating Stimulus Polarity, made available in order to minimize polarization of the stimulus electrodes. Intended to provide quicker recovery of the EEG amplifiers after stimulus, this option allows the first pulse of each pulse-pair to be made alternately positive and negative.

- The S12X keeps a running log of stimulus time and parameters in internal memory, in a format easily transferred to a USB flash drive or equivalent via the slave USB port on the S12X.

The ESAx electrode switch array has no function other than speeding up the process of functional brain mapping during presurgical and surgical workups. The optical relays are powered by the same isolated power supply in the S12X, and do not affect the stimulus waveform or isolation except to add approximately 100 ohms resistance to the stimulation circuit. The ESAx is essentially the same in functionality, effectiveness, and performance as the EMU-128S MODEL EX-NW-128S, marketed by XLTEK a division of Natus Medical, Inc., and authorized by 510(k) #K040360, and the EEG-1100A Switch Box, marketed by Nihon Kohden America, Inc., and authorized by 510(k) #K073491. All three are intended to switch external signals, as those of an electrical stimulation unit, to the appropriate electrodes. The only significant difference is that the XLTEK EM128S MODEL EX-NW128S switch matrix is incorporated into the XLTEK 128 channel EEG head box, whereas the Nihon Kohden EEG-1100A and the ESAx are external switches to the EEG amplifiers.

Conclusion from test data demonstrating Safety, Effectiveness, and Performance:

In house testing shows that the S12X meets design and performance functional requirements. The test data also demonstrates substantial equivalence with the predicate devices is so far as range of available stimulus outputs is concerned. The small extensions of available current from 10 to 15 milliamperes for pulses equal to or less than 1 millisecond are still within the 20 micro-joule charge per pulse limit of the OCS-1 predicate device.

The additional available compliance voltage from 20 to 30 volts is necessary to support the increased current from 10 ma in the OCS-1 to 15 ma in the S12X. Specifications that limit the maximum pulse frequency at 1 and 2 millisecond pulse widths to 50 Hz act to keep the maximum power output within the 60 milliwatt limit.

John B. Chatten, President
Chatten Associates, Inc.

September 5, 2008
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Chatten Associates, Inc.
% Mr. John Chatten
1094 New Dehaven Avenue
West Conshohocken, Pennsylvania 19428

Re: K082629
Trade Name: S12X with ESAx Option
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: II
Product Code: GYC
Dated: June 17, 2009
Received: June 19, 2009

Dear Mr. Chatten:

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): _____

Device Name: S12X with ESAx Option, Chatten Associates, Inc.

Indications for Use:

The S12X Cortical Stimulator is intended for Intraoperative cortical stimulation mapping to aid in cortical resections in the vicinity of essential cortex. The device is intended for use only by medically trained and qualified personnel, within a hospital or medical environment. The ESAx option is intended for use with the S12X for facilitating the switching of the patient electrodes.

Prescription Use ___X____ (Part 21 CFR 801 Subprt D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K082629