

X072964

## 510(k) Summary

DEC 30 2008

Company Name: Cardinal Health, Inc.  
NeuroCare  
5225 Verona Road, Building 2  
Madison, WI 53711

Device Name: Nicolet Cortical Stimulator

510(k) Sponsor, Contact:  
Cardinal Health, Inc.  
NeuroCare  
5225 Verona Road  
Madison, WI 53711  
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Summary Date: January 2, 2009

Common Name: Cortical Stimulator

Classification Name: Cortical Electrode, CFR 882.1310, Product Code: GYC, Class II

Predicate Device(s): K924226 Ojemann Cortical Stimulator  
K040360 XLTEK EMU128 Switch Matrix

### 1.0 Description of Device

The Nicolet Cortical Stimulator supports clinician guided, intermittent electrical stimulation of the brain cortex to support diagnostic and surgical procedures. The cortical stimulation energy is applied through commercially available cortical electrodes (strip and grid electrodes) of a minimum 2.3 mm diameter and a Cardinal Health, NeuroCare stimulation probe. All stimulation is temporary and intermittent, applied in support of functional brain mapping procedures during treatment of patients with seizure disorder.

The Nicolet Cortical Stimulator is a constant current stimulator. The stimulation current and frequency of stimulation is selected by the user. The Nicolet Cortical Stimulator (Cortical Stimulator) consists of two components:

- 1) Stimulus Switching Unit and
- 2) Cortical Stimulator Control Unit.

The Cortical Stimulator Control Unit (CSCU) is powered by an external power supply. The CSCU provides the current stimulation source. The Stimulus Switching Unit (SSU) directs the stimulation to selected electrodes.

The Cortical Stimulation Control Unit can be used in a stand-alone mode with stimulus provided through the Cardinal Health, NeuroCare stimulation probe. Alternatively the Cortical Stimulation Control Unit can be connected to the Stimulation Switching Unit. When the Stimulus Switching Unit is attached, the Stimulus Switching Unit interfaces between the Nicolet C64 Electroencephalography (EEG) amplifier and the amplifier's associated headbox. The headbox provides the interface between the amplifier and the brain contacting electrodes.

### **1.1 Clinical Application**

Prior to and during a surgical procedure to remove epileptic foci or a tumor of the brain, a cortical mapping procedure may be applied. Cortical stimulation may be applied to determine epileptic seizure foci that need to be surgically removed, tissue excised, as the foci are not managed with medications. The cortical stimulator is used with intra cranial cortical electrodes in the form of strips and/or grids temporarily placed on the surface of the patient's cerebral cortex. Having established a "focus" for the patient's epilepsy, the physician performs a number of procedures to establish if surgery is a viable option. Cortical mapping is one of those procedures. Cortical stimulation in support of cortical mapping may be applied during the monitoring period, in the patient epileptic monitoring area.

During cortical mapping electrical stimulation of the patient's cortex is performed through pairs of electrodes temporarily placed on the surface of the brain or by a hand held bipolar stimulator probe. The electroencephalograph (EEG) is recorded during the procedure and the patient is observed in person and through video so as to note and document clinical signs, behavioral changes and other possible effects, such as speech changes. Thus, the surgeon is able to identify eloquent brain areas and can avoid these if resection of brain tissue is performed.

The Cortical Stimulator is used in hospitals and clinical environments such as operating rooms, Neurology Clinics and Epilepsy Labs to support clinical evaluation of brain function.

## 2.0 Intended use of Device

The intended use of the Cortical Stimulator Unit is:

The Cortical Stimulator is intended for use in functional brain mapping procedures during treatment of patients with seizure disorder, providing stimulation via electrode pairs or a hand held bipolar probe.

## 3.0 Technological Characteristics

The technical characteristics of the Cortical Stimulator are equivalent to those of the predicate devices. The following table summarizes equivalence.

Feature	Cortical Stimulator Under Review	Predicate Ojemann Cortical Stimulator (K924226)	Predicate XLTEK EMU128 Switch Matrix (K040360)	Comments
Intended Use, Indications for Use	The Cortical Stimulator is intended for use in functional brain mapping procedures during treatment of patients with seizure disorder, providing stimulation via electrode pairs or a hand held bipolar probe.	The OCS-I is intended for use during surgical procedures such as placement of electrodes and brain mapping during treatment of patients with seizure disorder.	The EMU128 Switch Box used with the EMU128S electroencephalograph system to support electrode switching for brain mapping studies.	Equivalent  The predicate Ojemann Cortical Stimulator is a constant current stimulation source. The predicate EMU128 Switch Box provides switching of an external stimulation source to electrodes.
Constant Current Stimulator	Yes	Yes	Not Applicable An external stimulator is applied to this switching device to support stimulation.	Same
Maximum Stimulation Charge	15 micro-Coulomb	20 micro-Coulomb	Not Applicable An external stimulator is applied to this switching device to support stimulation.	Equivalent  The maximum stimulation charge applied is lower than the predicate Ojemann Cortical Stimulator

<b>Feature</b>	<b>Cortical Stimulator Under Review</b>	<b>Predicate Ojemann Cortical Stimulator (K924226)</b>	<b>Predicate XLTEK EMU128 Switch Matrix (K040360)</b>	<b>Comments</b>
Current Stimulation Range	0.1 to 15 mA (peak) Constant Current	0 to 10 mA (peak) Constant Current	Not Applicable An external stimulator is applied to this switching device to support stimulation.	Equivalent  The total stimulation energy applied is limited to a maximum of 15 micro-Coulomb (15 mA at 1 msec). This is less than the predicate Ojemann Cortical Stimulator 20 micro-Coulomb (10 mA at 2 msec).
Stimulation Frequency	1 to 100 Hz	5, 10, 20, 50, 75, 100 Hz	Not Applicable An external stimulator is applied to this switching device to support stimulation.	Equivalent
Stimulation Pulse Width Duration	0.1 to 1.0 msec per phase	0.1 to 2.0 msec per phase	Not Applicable An external stimulator is applied to this switching device to support stimulation.	Equivalent

#### **4.0 Data Summary**

Testing of the Nicolet System with the Cortical Stimulator was performed in compliance with the Cardinal Health, Inc. NeuroCare design control process. Testing included:

1. Software and hardware verification and validation, and
2. Safety standard compliance.

A summary of scientific literature supporting the safety of the Nicolet Cortical Stimulator was provided.

#### **5.0 Conclusions**

The safety and effectiveness of the Nicolet Cortical Stimulator was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Nicolet Cortical Stimulator is the same as the predicate devices. No new questions of safety or effectiveness are raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Rockville MD 20850

Cardinal Health, Inc.  
% Quality & Regulatory Associates, Inc.  
Mr. Gary Syring  
800 Levanger Lane  
Stoughton, Wisconsin 53589

Re: K072964

DEC 30 2008

Trade/Device Name: Nicolet Cortical Stimulator  
Regulation Number: 21 CFR 882.1310  
Regulation Name: Cortical electrode.  
Regulatory Class: Class II  
Product Code: GYC, ETN  
Dated: December 23, 2008  
Received: December 29, 2008

Dear Mr. Syring:

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 such 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); 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.

Page 2 – Mr. Gary Syring

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Nicolet Cortical Stimulator

Indications for Use:

The Cortical Stimulator is intended for use in functional brain mapping procedures during treatment of patients with seizure disorder, providing stimulation via electrode pairs or a hand held bipolar probe.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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