K991012

510(k) SUMMARY
as required per 807.92(c)

2. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: March 19, 1999

3. Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY EEG Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Electroencephalograph	OLT, ORT	II	882.1400
	OMC		

2. Predicate Device Identification:

Aspect Medical Systems, Inc.
Model A-1000 EEG Monitor
510(k) K963644

3. Device Description:

The INFINITY EEG pod is an addition to Siemens SC9000/SC8000/SC7000/SC9000XL INFINITY patient monitoring series. When connected to an INFINITY EEG pod, an INFINITY Modular Bedside Monitor is capable of measuring up to four channels of EEG waveforms. Each waveform has its own parameter box, and each parameter box displays up to three parameters that can be trended, printed, and displayed on a central station.

4. Intended Use:

To monitor the state of the brain by data acquisition of EEG signals.

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Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

5. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device	Applicant	Explanation of Differences
Manufacturer	Aspect Medical Systems, Inc. A-1000 EEG Monitor and A-1050 EEG Monitor	Siemens Medical Systems Infinity EEG Pod	
510(k) Number	K963644	To be assigned	
Intended Use	To monitor the state of the brain by data acquisition of EEG signals	Same	
Intended Population	All patient populations	Same	
Intended Environment	The intensive care unit, operating room and clinical research	An environment where patient care is provided by Healthcare Professionals	
Computed Parameters	Total Power	Same	
	Delta, Theta, Alpha, Beta Power	Same	
	Spectral Edge Frequency	Same	
	Median Frequency	Same	
	Burst Suppression ratio	Same	
	Power of user defined Band 1	No	Parameter not supported
	Power of user defined Band 2	No	
	Asymmetry	No	
	Bispectral Index	No	
	EMG Power Band 1	No	
	EMG Power Band 2	No	

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6. Assessment of non-clinical performance data for equivalence: Exhibit U

7. Assessment of clinical performance data for equivalence: Exhibit V

8. Biocompatability:
Not applicable

9. Sterilization:
Not applicable

10. Standards and Guidances: FDA Electroencephalograph Devices Guidance for 510(k) Content, Draft Document Version 1.0, November 3, 1997

IEC 601-2-26: 1994, Medical Electrical Equipment: Part 2: Particular Requirements for the Safety of Electroencephalographs

COMPANY CONFIDENTIAL

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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

Ms. Penelope H. Greco
Regulatory Submissions Manager
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, Massachusetts 01923

APR - 9 2012

Re: K991012
Trade/Device Name: Siemens INFINITY EEG Pod
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, ORT, OMC
Dated (Date on orig SE ltr): March 19, 1999
Received (Date on orig SE ltr): March 26, 1999

Dear Ms. Greco:

This letter corrects our substantially equivalent letter of June 24, 1999.

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

510(k) Number (if known): K991012

Device Name: Siemens INFINITY EEG Pod

Indications for Use:

Siemens INFINITY EEG Pod is indicated for use in the adult, pediatric and neonatal populations, in an environment where patient care is provided by healthcare professionals, i.e. Physicians, Nurses, Technicians, when the professional determines that the device is required to monitor the state of the brain by data acquisition of EEG signals.

MRI Compatibility Statement:
The Siemens INFINITY EEG Pod is not intended for use in a MRI magnetic field.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991012