

**510(k) Summary of Safety and Effectiveness** JUN 24 1997  
**Somnus Medical Technologies, Inc.™**  
**Model 215 Electrosurgical Generator and Accessories**

K 971711

**Intended Use:**

The Somnus™ Model 215 Electrosurgical Generator and Accessories are intended for use with the Somnus Tissue Coagulating Electrodes for the coagulation of tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

**Submitted by:**

Somnus Medical Technologies, Inc.  
285 North Wolfe Road  
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**Contact Person:**

Eve A. Conner, Ph.D.  
Vice President  
Clinical and Regulatory Affairs  
Telephone: (408) 617-3424

**Date Summary Prepared:**

May 6, 1997

**Name of the Device:**

Proprietary Name: Somnus™ Model 215 Electrosurgical  
Generator and Accessories

Common/Usual Name: Electrosurgical Generator and  
Accessories

Classification Name: Electrosurgical Device (per 21 CFR  
878.4400)

**Predicate Devices:**

Somnus Model 215 Electrosurgical Generator  
Erbe ICC 200  
Erbe ICC 50  
VidaMed 50  
VidaMed 7205

**Description:**

The Somnus™ Model 215 Electrosurgical Generator is an electrosurgical generator with controls for power delivered, time of energy delivery and in the automatic mode, maximum temperature. The unit has readouts for total energy delivered, impedance, number of active channels and temperature for up to 6 thermocouples. Connectors on the front panel include connectors for electrodes and a footpedal.

Accessories included with the generator include a line power cable, single pedal footpedal an adapter for a dispersive electrode.

**Statement of Intended Use:**

The Somnus Model 215 Electrosurgical Generator and Tissue Coagulating Electrodes are intended for use in the coagulation of tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

**Comparison to Predicate Devices:**

The Somnus Model 215 Electrosurgical Generator and Accessories has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.



JUN 24 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Eve A. Conner, Ph.D.  
Vice President, Clinical and Regulatory Affairs  
Somnus Medical Technologies, Inc.  
285 N. Wolfe Road  
Sunnyvale, California 94086

Re: K971711  
Trade Name: Somnus™ Model 215 Electrosurgical Generator  
Regulatory Class: II  
Product Code: GEI  
Dated: May 6, 1997  
Received: May 8, 1997

Dear Dr. Conner:

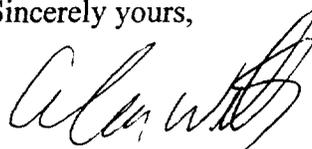
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): ~~Not Yet Assigned~~ K971711

Device Name: SOMNUS™ MODEL 215 ELECTROSURGICAL GENERATOR AND ACCESSORIES

**Indications For Use:**

The Somnus Model 215 Electrosurgical Generator, in combination with various Somnus electrodes, is indicated for the coagulation of tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

**Contraindications for Use:**

The use of the Somnus Model 215 Electrosurgical Generator and Accessories is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971711

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  X  OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)