

**510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.TM
Model 615 Electrosurgical Generator and Accessories**

K 9705 76

Intended Use:

The SomnusTM Model 615 Electrosurgical Generator and Accessories are intended for use with the Somnus Soft Tissue Coagulating Electrodes for the coagulation of soft tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted by:

Somnus Medical Technologies, Inc.
995 Benecia Avenue
Sunnyvale, CA 94086
Tel: 408.773.9121
Fax: 408.773.9137

Contact Person:

Eve A. Conner, Ph.D.
Vice President
Clinical and Regulatory Affairs
Telephone: (408) 524-6263

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Name of the Device:

Proprietary Name: SomnusTM Model 615 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
VidaMed Model 50
Vidamed Model 7205
Erbe ICC 50

Description:

The Somnus™ Model 615 Electrosurgical Generator is an electrosurgical generator has controls for maximum temperature, power delivered, energy delivered and time of energy delivery. The unit has readouts for total energy delivered, impedance, maximum power, temperature for up to 18 thermocouples. Connectors on the front panel include connectors for electrodes and a footpedal.

Accessories included with the generator include a line power cable and a single pedal footpedal.

Statement of Intended Use:

The Somnus Model 615 Electrosurgical Generator and Soft Tissue Coagulating Electrodes are intended for use in the coagulation of soft tissue.

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

Comparison to Predicate Devices:

The Somnus Model 615 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.