

**510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.TM
Model 225 Electrosurgical Generator and Accessories**

K963772

OCT 23 1996

Intended Use:

The SomnusTM Model 225 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
Digital Pager: 1-800-586-1439

Date Summary Prepared::

September 16, 1996

Name of the Device:

Proprietary Name: SomnusTM Model 225 Electrosurgical
Generator and Accessories
Common/Usual Name: Electrosurgical Generator and
Accessories
Classification Name: Electrosurgical Device (per 21 CFR
878.4400)

000051

Predicate Devices:

Erbe ICC 200
Erbe ICC 50
ZoMed
VidaMed

Description:

The Somnus™ Model 225 Electrosurgical Generator is an electrosurgical generator has controls for power delivered and time of energy delivery. 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, cables to connect the electrodes to the generator and a dispersive electrode.

Statement of Intended Use:

The Somnus Model 225 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 225 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.