510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.™
Somnoplasty™ System

Intended Use:
The Somnoplasty™ System is intended for the reduction of the incidence of airway obstructions in patients suffering from UARS or OSAS.

Submitted by:
Somnus Medical Technologies, Inc.
285 North Wolfe Road
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) 773-9121

Date Summary Prepared:
July 31, 1998

Name of the Device:
Proprietary Name: Somnus™ Medical Technologies, Inc.
Somnoplasty™ System

Common/Usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical Device (per 21 CFR 878.4400)
Predicate Devices:
Somnus Model S2 Electrosurgical Generator
Somnus Tissue Coagulating Electrode Models 1000, 1010, 1200,
2000, 2010, 3000, 30XX, 6000

Description:
The Somnoplasty™ System is comprised of an Electrosurgical (RF)
Generator and Tissue Coagulating Electrodes. The RF Generator
has controls for target temperature, target energy, 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 3 thermocouples per channel. Connectors on the front
panel include connectors for coagulating and dispersive electrodes
and a footpedal. The electrodes are provided with various
handpiece configurations to facilitate the placement of the needles
in the tissue to be ablated.

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

Statement of Intended Use:
The Somnoplasty™ System is intended for the reduction of the
incidence of airway obstructions in patients suffering from UARS
or OSAS.

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

Comparison to Predicate Devices:
The Somnoplasty™ System has been carefully compared to legally
marketed devices with respect to intended use and technological
characteristics. Performance validation testing, including a clinical
study, 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.
Eve A. Conner, Ph.D.
Vice President
Clinical and Regulatory Affairs
Somnus Medical Technologies, Inc.
285 North Wolfe Road
Sunnyvale, California 94086

Re: K982717
Trade Name: Somnoplasty™ System
Regulatory Class: II
Product Code: GEI
Dated: July 31, 1998
Received: August 04, 1998

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. 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,

[Signature]

Celina 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

Device Name: Somnoplasty System

Indications for Use:

The Somnoplasty System is intended for the reduction of the incidence of airway obstructions in patients suffering from UARS (Upper Airway Resistance Syndrome) or OSAS (Obstructive Sleep Apnea Syndrome).