JUL 17 1997

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

Intended Use:

The Somnoplasty™ System is intended for the coagulation (thermal ablation, tissue volume reduction) of soft tissue, including tissue in the uvula/soft palate and may reduce the severity of snoring in some individuals. The system is intended for use by qualified medical personnel trained in the use of RF tissue ablation.

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) 773-9121

Date Summary Prepared::

July 8, 1997

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)

000003

Predicate Devices:

Somnus Model 215 Electrosurgical Generator
Somnus Tissue Coagulating Electrode Models 1000, 2000

Description:

The Somnoplasty™ System is comprised of an Electrosurgical (RF) Generator and Tissue Coagulating Electrodes. The RF 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 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, single pedal footpedal and an adapter plug to accommodate dispersive electrodes from various manufacturers.

Statement of Intended Use:

The Somnoplasty™ System is intended for coagulation of soft tissue, including the uvula/soft palate and may reduce the severity of snoring in some individuals.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 17 1997

Re: K971450
Trade Name: Somnoplasty™ System
Regulatory Class: II
Product Code: GEI
Dated: April 17, 1997
Received: April 21, 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.

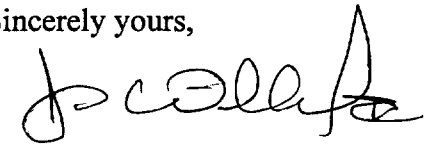
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , 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) 594-4595. 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K#971450

Device Name: SOMNOPLASTY™ SYSTEM

Indications For Use:

The Somnoplasty System is intended for coagulation (thermal ablation, tissue volume reduction) of soft tissue, including the uvula/soft palate and may reduce the severity of snoring in some individuals.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971450