510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.™
Electrode Bending Tool

JUN 18 1997

K970809

Intended Use:

The Somnus™ Electrode Bending Tool is an accessory to the Somnus Bendable Tissue Coagulating Electrode. The Bending Tool is intended for use by qualified medical personnel trained in the use of Somnus Tissue Coagulating Electrodes.

Submitted by:

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Contact Person:

Eve A. Conner, Ph.D.
Vice President
Clinical and Regulatory Affairs
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Date Summary Prepared::

March 3, 1997

Name of the Device:

Proprietary Name:	Somnus™ Electrode Bending Tool
Common/Usual Name:	Electrosurgical Device Accessory
Classification Name:	Electrosurgical Device (per 21 CFR 878.4400)
Classification Panel:	General Surgery Devices

Common/Usual Name: Electrosurgical Device Accessory

Classification Name: Electrosurgical Device (per 21 CFR 878.4400)

Classification Panel: General Surgery Devices

Predicate Devices:

Somnus Bendable Tissue Coagulating Electrode, 510(k) Premarket Notification #K961133

Description:

The Somnus™ Bendable Tissue Coagulating Electrode is used to deliver radiofrequency (RF) energy for selective thermal ablation of tissues. The needle is deployed from a guide tube. The guide tube can be bent using the Electrode Bending Tool to allow deployment of the needle at angles ranging from 0 to 45°.

Statement of Intended Use:

The Somnus Model 1000 - Needle Sleeve Bending Tool is intended to change the angle of deployment of the needle for the Model 1000 - Single Needle Coagulating Electrodes by creating a radial bend in the needle sleeve.

The Somnus Bendable Tissue Coagulating Electrodes are intended for use in the coagulation of tissue. The Bending Tool is intended for use by qualified medical personnel trained in the use of Somnus Tissue Coagulating Electrodes.

Comparison to Predicate Devices:

The Somnus Bendable Tissue Coagulating Electrode with Bending Tool 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eve A. Conner, Ph.D.
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JUN 18 1997

Re: K970809
Trade Name: Somnus™ Electrode Bending Tool
Regulatory Class: II
Product Code: GEI
Dated: May 1, 1997
Received: May 6, 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,

for 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): K970809

Device Name: SOMNUS™ ELECTRODE BENDING TOOL

Indications For Use:

The Somnus Model 1000 - Needle Sleeve Bending Tool is intended to change the angle of deployment of the needle for the Model 1000 - Single Needle Coagulating Electrodes by creating a radial bend in the needle sleeve.

This device is intended for use by qualified medical personnel trained in the use of Somnus Tissue Coagulating Electrodes.

Contraindications for Use:

There are no known contraindications for the use of this accessory with the Bendable Tissue Coagulating Electrode.

(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)

(Division Sign-Off) (Optional Format 1-2-96)
Division of General Restorative Devices
510(k) Number K970809