

K 970837 JAN - 9 1998

510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.™
Model 6000 Disposable Tissue Coagulating Electrode

Statement of Intended Use:

The Somnus™ Model 6000 Disposable Tissue Coagulating Electrode is intended for use in the coagulation of tissue.

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

Submitted by:

Somnus Medical Technologies, Inc.
995 Benecia Avenue
Sunnyvale, CA 94086
Tel: 408.773.9121
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Contact Person:

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

Date Summary Prepared::

March 4, 1997

Name of the Device:

Proprietary Name: Somnus™ Model 6000 Disposable
Tissue Coagulating Electrode

Common/Usual Name: Electrosurgical Device Accessory

Classification Name: Electrosurgical Device (per 21 CFR
878.4400)

Predicate Devices:

Somnus Model 3000 Disposable Tri-Needle Coagulating Electrode

Description:

The Somnus™ Model 6000 Disposable Tissue Coagulating Electrode is a modification of the Model 3000 Disposable Tri-Needle Coagulating Electrode cleared for commercial distribution under 510(k) #K963884. The Model 6000 device has a maximum of six needles configured in two rows of three needles each. The Model 3000 has a maximum of 3 needles in a single row. Both devices provide a reliable method of performing coagulation on target areas of tissue using a handle grip for ease of placement. The configuration of the handle grip of the Model 6000 and Model 3000 are identical.

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Comparison to Predicate Devices:

The Somnus 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eve A. Conner, Ph.D.
Vice President Clinical and Regulatory Affairs
Somnus Medical Technologies, Incorporated
285 North Wolfe Road
Sunnyvale, California 94086

JAN - 9 1998

Re: K970837
Trade Name: Somnus Model 6000 Disposable Tissue Coagulating Electrode
Regulatory Class: II
Product Code: GEI
Dated: December 8, 1997
Received: December 9, 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.

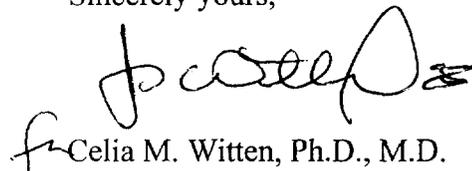
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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

510(k) Number (if known): K970837

Device Name: Somnus™ Model 6000 Disposable Tissue Coagulating Electrode

Indications For Use:

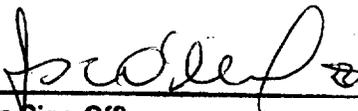
The Somnus Model 6000 Disposable Tissue Coagulating Electrode is intended for the coagulation of tissue.

(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 K970837