

JAN 30 1998

K973701

510(k) Summary of Safety and Effectiveness
Somnus Medical Technologies, Inc.™
Reusable Cable for use with Somnus Tissue Coagulating
Electrodes

Statement of Intended Use:

The Somnus™ Tissue Coagulating Electrodes are intended for coagulation of soft tissue.

Submitted by:

Somnus Medical Technologies, Inc.
285 N. 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:

September 26, 1997

Name of the Device:

Proprietary Name: Somnus™ Tissue Coagulating
Electrodes and Somnus Reusable Cable

Common/Usual Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Device (per 21 CFR
878.4400)

Predicate Devices:

Somnus Medical Technologies, Inc. Tissue Coagulating Electrodes

Description:

The Somnus™ Tissue Coagulating Electrodes and Reusable Cables provide a reliable means of coagulating soft tissue.

Comparison to Predicate Devices:

The Somnus Tissue Coagulating Electrodes and Reusable Cables have 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

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

Re: K973701
Trade Name: Models RC-1 and RC-2 Reusable Cables
Regulatory Class: II
Product Code: GEI
Dated: November 21, 1997
Received: January 9, 1998

Dear Dr. Conner:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

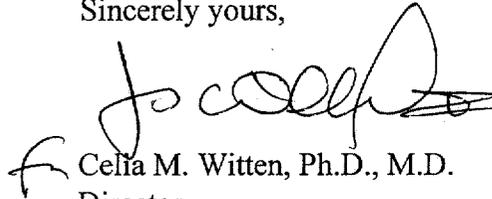
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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.

Page 2 - Dr. Conner

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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): K973701

Device Name: Models RC-1 and RC-2 Reusable Cables

Indications For Use:

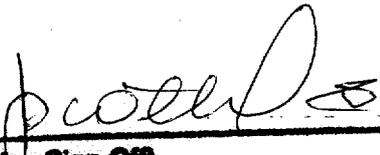
The Somnus Model RC-1 and RC-2 Reusable Cables are intended to provide an electrical connection between the Somnus Medical Technologies Model 1100, 1110 and 2110 Tissue Coagulating Electrodes and the Somnus Medical Technologies Electrosurgical (RF) Generators

(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 K973701