OCT 29 1997

K973297

Appendix 1

Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name	Electrosurgical Device and Accessories
Device Trade Name:	Cosman Coagulator CC-1
Intended Uses	To coagulate tissue.
Predicates Device:	Radionics CBC-1 Bipolar Coagulator and Bipolar Forceps; Codman Malis CMC-III and Bipolar Forceps; Valleylab Force 40 with Current Monitor, Bipolar and Monopolar Forceps; F.L. Fischer G50 Bipolator and Bipolar Forceps; Somnus Model 3000 Tri-Needle Electrode; Zomed Model 30-6 Multielectrode Array;
Establishment Name and Address:	Radionics, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	William Rittman (781) 272-1233
Establishment Registration Number:	1219140
Performance Standard	None established under Section 514.

Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

Safety Summary

The Radionics CC-1 Cosman Coagulator is an electrosurgical device with a microprocessor and accessory electrodes. The features of the CC-1 are included in one or more of the predicate devices. The system and unit testing results provided in this premarket notification verify that the CC-1 is accurate and reliable. Audio and visual indicators and displays inform the user regarding the proper function of the CC-1. In addition, self-test routines check the software and front panel LEDs upon power-up.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and error conditions as well as general instructions for the proper operation of the device. This information promotes safe and effective use of the device.

Description of the Device and Basis for Substantial Equivalence

The CC-1, addressed in this premarket notification, has the same intended use and technological characteristics as the commercially available Radionics CBC-1, Codman Malis CMC-III, Fischer G50 and Valleylab Force 40 devices. Like these devices, the CC-1 is comprised of a radiofrequency generator with a microprocessor and accessory electrodes. The features of the generator include manual, timed, automatic temperature and automatic power control. The CC-1 also displays and/or monitors: impedance, temperature, power and current. The maximum power output is 200 Watts. Electrodes include monopolar, bipolar, reusable, disposable, irrigating and non-irrigating types. These features are all included in one or more of the predicate devices. Radionics believes that the information and testing provided in this premarket notification clearly describe the CC-1 Cosman Coagulator and accessories and demonstrate that it is equivalent to the mentioned commercially marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1997

Mr. William Rittman
President
Radionics Instruments, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K973297
Trade Name: Cosman Coagulator (CC-1) System
Regulatory Class: II
Product Code: GEI
Dated: August 29, 1997
Received: September 2, 1997

Dear Mr Rittman:

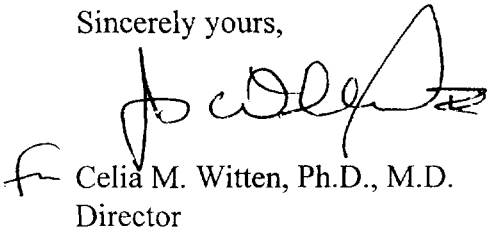
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known): K973297

Device Name: CC-1 Cosman Coagulator

Indications For Use:

The Cosman Coagulator (CC-1) and accessories are indicated for general surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973297

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)