

Appendix 1

MAR 12 1997

Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name	Radiofrequency Lesion Generator
Device Trade Name:	RFG-3CF
Intended Uses	To create lesions during neurosurgical lesion procedures.
Predicate Device:	Radionics RFG-3C Lesion Generator; Fischer Neuro N50 System; Leksell Neuro Generator, LNG 30-T; Grass Instruments' Stimulator Model S5 with Constant Current Unit, Accessory Model CCU1
Establishment Name and Address:	Radionics, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	Amy J. LaForte, Ph.D. (617) 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 RFG-3CF lesion generator is a modification of the RFG-3C lesion generator. The stimulator feature has been modified to include a constant current mode and the stimulation parameter specification for frequency has been increased to 200 Hz. The system and unit testing results provided in this premarket notification verify that the RFG-3CF is accurate and reliable. Audio and visual indicators and displays inform the user regarding the proper function of the RFG-3CF. In addition, new self-tests routines have been included to check the software and front panel LEDs upon power-up. In addition, a watchdog timer has been added which will shut down the RFG-3CF and re-boot the software, if the software was not functioning properly.

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 RFG-3CF, addressed in this premarket notification, has the same intended use and technological characteristics as the commercially available Radionics RFG-3C, Fischer Neuro 50, and Leksell LNG 30-T generators. Like these devices, the RFG-3CF is a radiofrequency lesion generator used to coagulate or lesion nervous tissue. In addition, the stimulator feature of the RFG-3CF has the same intended use and technological characteristics as the that of the predicate devices mentioned as well as the Grass Stimulator with Constant Current Unit. The stimulator feature is used to stimulate nerve cells to aid in the placement of electrodes. The stimulator is the major feature modification of the RFG-3CF from the RFG-3C. In the RFG-3CF, the user may choose

from constant voltage or constant current stimulation. The user may also select the stimulator parameters such as pulse amplitude, duration and frequency. Radionics believes that the information and testing provided in this premarket notification clearly describe the modifications to the RFG-3CF (from the RFG-3C) and demonstrate that it is equivalent to the mentioned commercially marketed predicate devices.