

K963577

NOV 21 1996

I General Information

Proprietary Trade Name: Radionics Sluijter-Mehta Cannula
Model Number: RSM-C
Common Name: Disposable cannula for radiofrequency electrode
Manufacturing Facility Address: Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803
Establishment Registration Number: 1219140
Contact Person: Amy LaForte, Ph.D.
(617) 272-1233
Classification: Class II
Predicate Devices: SMK Cannula (K870028); and
Radionics TIC Cannula (pre-amendment).
Intended Use: The RSM-C is intended for use in radiofrequency (RF) heat
lesion procedures for relief of pain. This is the same
intended use as the SMK Cannula and TIC Cannula.
Performance Standard: No applicable performance standards have been issued
under section 514 of the Food, Drug, and Cosmetic Act.
Sterilization Site: STS
7500 W. Henrietta Road
PO. Box 349
Rush, NY 14543
(716) 533-1672

The RSM-C Radionics Sluijter-Mehta Cannulae are insulated disposable cannulae designed for use with a Radionics Radiofrequency Lesion Generator to create heat lesions for relief of pain. These cannulae are compatible with the commercially available Radionics SMK-TC thermocouple electrodes. They are used in the same way as the commercially available Radionics SMK-C Cannulae.

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

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

General Safety and Effectiveness Concerns

RSM-C Radionics Sluijter-Mehta Cannula labeling contains instructions for the proper use of this device. It includes a description of the product, directions for use, and applicable safety information. These instructions ensure safe and effective use of the device when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The RSM Sluijter-Mehta Cannula addressed in this premarket notification has similar intended use and technological characteristics as the commercially available Radionics SMK Cannula (K870028). The insulating material is the same as that on the commercially available Radionics TIC Cannula, a pre-amendment device.