APPENDIX 1: Summary of Safety and Effectiveness

I. General Information

Device: Depth Electrode Placement Kit

Device Trade Name: Cosgrove Depth Electrode Kit (CDEK)

Classification: Class II

Intended Uses: The Cosgrove Depth Electrode Kit (CDEK) allows the user to place and secure epilepsy electrodes via a lateral orthogonal surgical approach or stereotactically using Radionics CRW and BRW Stereotactic Arc Systems which have been cleared through the FDA.

Predicate Device   Todd-Wells Stereotaxic Guide and Accessories, (pre-amendment); manufactured by Radionics
Radionics CRW Stereotactic Arc System (K944463);
Radionics BRW Stereotactic Arc System (K811452);
Radionics Bipolar Forceps, (pre-amendment)

Establishment Name and Address: Radionics, Inc.
22 Terry Ave.
Burlington, MA 01803

Performance Standard: None established under Section 514 of the Food, Drug and Cosmetic Act.

Establishment registration number: 1219140

Contact Name and Phone: Amy J. LaForte, Ph.D. (617) 272-1233

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

Radionics CDEK labeling contains instructions for the proper use of these devices when placing and securing epilepsy electrodes. 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 CDEK Cosgrove Depth Electrode Kit addressed in this premarket notification has similar intended use and technological characteristics as accessories provided in the commercially available Radionics Todd-Wells Stereotaxic Guide (a pre-amendment device), the Radionics CRW and BRW Stereotactic Arc Systems, and Radionics Bipolar Forceps (a pre-amendment device).