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UTAH MEDICAL
PRODUCTS INC.



Summary of Safety and Effectiveness

The Aspiration/Coag Electrode is substantially equivalent to Utah Medical Products, Inc.'s DBL-311 and DBL-511 ball electrodes used for coagulation, combined with aspiration of the Valleylab E2505-10FR disposable electrode. The device consists of a stainless steel spherical ball electrode and an attached external PEBAX® aspiration tube.

The posterior end of the device fits snugly into a standard electrosurgical pen which is connected to an FDA approved electrosurgical generator and standard vacuum suction system. When used according to the instructions for use, in the hands of a trained user, the device provides an effective tool for allaying excessive bleeding by fulgurating and desiccating tissue damaged in electrosurgical procedures.

Materials that comprise the Aspiration/Coag Electrode are essentially the same as those used in other similar devices, and were selected based on properties of biocompatibility, compatibility with gamma sterilization, conformance with commonly used medical grade plastics and other materials, ease of processing and low cost.

Biocompatibility and sterilization information is available from Utah Medical Products, Inc. upon request.

A handwritten signature in black ink, appearing to read 'Kevin L. Cornwell', is written in a cursive style.

Kevin L. Cornwell
President & CEO