

OCT - 2 1996

510(k) Summary of Safety and Effectiveness

K953983

1.0 Classification Name:

Electrode, Electrosurgical

2.0 Common Name:

Roller electrode, Coagulation electrode, Electrosurgical Electrode

3.0 Trade Name:

Electrosurgical Vaporization (EVAP) electrode

4.0 Equivalence:

The EVAP electrodes are substantially equivalent to electrodes currently sold by Richard Wolf, as well as electrodes sold by ProSurg (k946377) and ACMI/Circon (no 510(k) available).

5.0 Description:

The EVAP electrode is an electrosurgical device made of medical grade stainless steel, teflon, new silver and Hytrel tubing. Some EVAP versions have gold plated rollers.

6.0 Intended Use:

The EVAP roller electrodes can be used for removing/vaporization/ablation of soft tissue. For example; on the prostate or on myomas. The electrodes may also be used for coagulation.

7.0 Technological Characteristics:

The only variation from the existing electrodes is the addition of grooves and gold plating on various versions of the roller. The insulating material has been changed to Hytrel 8236 thermoplastic polyester elastomer.

8.0 Performance Data:

Devices were tested to meet the appropriate sections of the ANSI/AAMI standard on High Frequency Devices.

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9.0 Clinical Tests:

Using Canine Models, it has been shown that coagulation depth increases with higher wattage but does not exceed 2-3mm. Irrigation reduces the risk of heat damage. Long term morbidity and healing were not known.

10.0 Data Conclusion:

The Richard Wolf EVAP Electrode is equivalent to existing electrodes particularly those sold by ProSurg and ACMI/Circon.

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