

K 963338

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SAFETY AND EFFECTIVENESS SUMMARY

COMMON/USUAL NAME: Electrosurgical Electrodes

PROPRIETARY NAME: *unimed* Suction-Irrigation Electrode and *unimed* Sliding Sheath

CLASSIFICATION: CLASS II

MATERIALS: All materials used to manufacture the *unimed* Suction-Irrigation Electrode and *unimed* Sliding Sheath are non-toxic and have been used in other previously marketed devices.

DESCRIPTION: The *unimed* Surgical Products *unimed* Suction-Irrigation Electrode and *unimed* Sliding Sheath are electrosurgical devices designed for suction/irrigation as well as cutting and coagulating of soft tissue.

*unimed* Surgical Products intends to market the *unimed* Suction-Irrigation Electrode with five tip configurations. The tip configurations are the Spatula, J-Hook, L-Hook, Coagulator and Needle. The electrodes are available with a shaft diameter of 5mm and a working length of 28cm or 32 cm. The *unimed* Sliding Sheath will be marketed in one configuration in 28cm and 32cm lengths. The proximal end is designed to fit a standard monopolar cord.

SUBSTANTIAL EQUIVALENCE: The *unimed* Suction-Irrigation Electrodes and *unimed* Sliding Sheath are similar to other Suction-Irrigation Electrodes currently commercially available. Numerous electrodes with a variety of tip configurations are marketed by Cabot Medical and American Hydro-Surgical Instruments.