

K 97 0066

SAFETY AND EFFECTIVENESS SUMMARY

COMMON/USUAL NAME: Electrosurgical Electrodes

FEB 18 1997

PROPRIETARY NAME: *unimed* Coated Laparoscopic Electrode
unimed Coated Arthroscopy Electrode
unimed Coated Suction-Irrigation Electrode

CLASSIFICATION: CLASS II

MATERIALS: All materials used to manufacture the Coated Electrodes are non-toxic and have been used in other previously marketed devices.

DESCRIPTION: The *unimed* Coated Laparoscopic Electrode, *unimed* Coated Arthroscopy Electrode and the *unimed* Coated Suction-Irrigation Electrode are coated with Emralon 333 or Teflon 420-104. Both are dry lubricants which provide a low coefficient of friction and reduce eschar build-up during surgery and the need for higher power settings. Without eschar build-up that takes place with a standard stainless steel tip less scraping and inconvenience takes place resulting in greater OR efficiency.

Each coating is non-toxic, corrosion resistant, and therefore safe for the patient and the OR staff.

These electrosurgical devices are designed for cutting of soft tissue and coagulation. The electrodes are available in a variety of diameters, lengths and tip configurations.

The electrodes are available sterile, single use only.

SUBSTANTIAL EQUIVALENCE: This 510(k) notification represents the adding of a coating that is identical to the coatings on *unimed's* Coated Electrode (K962935) to *unimed* Electrodes identified as *unimed* Laparoscopic Electrodes (K945030) and *unimed* Suction-Irrigation Electrodes (K963338).