

K961069

ArthroCare Corporation
Sunnyvale, California
Premarket Notification
March 15, 1996

MAY 28 1996



X. Summary of Safety and Effectiveness

The ArthroCare Urologic Multi-electrode Electrosurgery System is a high frequency electrosurgical device intended for use in general urological surgery to resect soft tissue and provide hemostasis. The System is comprised of three components: the UroWand, the UroWand Cable, and the Controller. The UroWand, UroWand Cable and the Controller are virtually identical to the ArthroCare Probe, Probe Cable and Controller determined substantially equivalent in K943450 for the ArthroCare Arthroscopic Electrosurgery System. The technology is also substantially equivalent to that of the ArthroCare Bipolar Loop Electrode System (K955531).

Predicate electrode products and electrosurgical generators have been marketed since the 1950's by several different manufacturers such as Circon ACMI and Karl Storz. Other monopolar and bipolar electrosurgery devices have been cleared for market via 510(k)'s, such as the electrosurgery devices manufactured by Olympus America and Karl Storz-America, Inc. These products have been demonstrated to be safe and effective in resecting soft tissue during urological surgical procedures.

The ArthroCare Urologic Multi-electrode Electrosurgery System raises no new issues of safety or efficacy. The bipolar design of the ArthroCare UroWand incorporates the return electrode into the shaft of the device. This means that a patient ground pad is not required as with monopolar electrodes. The energy flows back to the Controller via the integral return electrode rather than through the patient's body to the grounding pad. In addition, the ArthroCare UroWand is designed to be operated in a physiological saline environment while the predicate products must be operated in a non-conductive environment, such as sterile water or glycine. This allows ArthroCare to achieve equivalent efficacy in tissue resection with less power requirements.

The materials used in the ArthroCare Urologic Multi-electrode Electrosurgery System are identical to those used in the ArthroCare Arthroscopic Electrosurgery System (K943450) and the ArthroCare Bipolar Loop Electrode System (K955531). Predicate devices use either stainless or titanium for the wire material of their electrosurgical electrodes. The materials used in the UroWand Cable are identical to those used in the Probe Cable (K943450 and K955531).

Bench testing has demonstrated equivalent performance characteristics between the ArthroCare UroWand and the ACMI Circon and Olympus America electrosurgical devices. In vivo arthroscopic animal studies have demonstrated that the depth of soft tissue alteration with the ArthroCare Arthroscopy System (which is

virtually identical to the ArthroCare Urological Multi-electrode Electrosurgery System), is similar to that of a standard monopolar electrosurgery device. In addition, the ArthroCare System meets applicable domestic and international safety requirements and standards.

By virtue of design, materials and function, the ArthroCare Urologic Multi-electrode Electrosurgery System is substantially equivalent to the predicate devices currently marketed in the United States.