

OCT - 8 1996

**X. 510(k) Summary**

*K963123*

**A. Name of Device**

Trade name: ArthroCare Arthroscopic Electrosurgery System  
980  
Common name: Electrosurgical Generator  
Classification name: Electrosurgical Cutting and Coagulation Device  
and Accessories (21 CFR 878.4400)  
  
Accessory to an Arthroscope (21 CFR 888.1100)

**B. Predicate devices**

<u>Device</u>	<u>Premarket Notification</u>
ArthroCare Arthroscopic Electrosurgery System 970	K943450
ArthroCare Arthroscopic Electrosurgery System 970 (Addition of Hip Indication)	K961747
ArthroCare Arthroscopic Electrosurgery System 970 (Addition of Wrist Indication)	K962321

**C. Device description**

The ArthroCare Arthroscopic Electrosurgery System 980 is comprised of three components: the Probe, the Probe Cable, and an electrosurgical generator called the Controller. The Probe Cable connects the Controller to the Probe. The Probe is provided in a variety of models, ranging in diameters from 1.5 mm to 4.5 mm with the distal tip of the probe as straight or bent at angles up to 90 degrees. The distal tip may be configured with multi-electrodes or loop electrodes. The Probe is supplied sterile and intended for single patient use. The Probe Cable is designed for repeat sterilization by either ethylene oxide gas or steam autoclaving methods, as selected by the user. The Controller is a high frequency electronic instrument. There is no software utilized in the operation of the Controller.

The ArthroCare Arthroscopic Electrosurgery System 980 is bipolar, incorporating a return electrode on the shaft of the device. This means that a return pad is not required for operation. The return energy in a bipolar device with an integral return electrode does not penetrate the tissue as in a monopolar device. In a monopolar device, the energy passes through the patient's body to reach the return pad.

*D. Intended use*

The ArthroCare Arthroscopic Electrosurgery System 980 is intended for use in arthroscopic surgical procedures of the knee, shoulder, ankle, elbow, hip and wrist for soft tissue resection and hemostasis.

*E. Technological characteristics*

The technological characteristics of the ArthroCare Arthroscopic Electrosurgery System 980 are the same as those of the ArthroCare Arthroscopic Electrosurgery System 970. The devices are substantially equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

*F. Summary*

By virtue of design, materials, function and intended use, the ArthroCare Arthroscopic Electrosurgery System 980 is substantially equivalent to the ArthroCare Arthroscopic Electrosurgery System 970 which is currently marketed in the United States.