

APR 14 1997

X. 510(k) Summary

K964849

A. *Name of Device*

Trade name: ArthroCare Dermal Electrosurgery System  
Common name: Electrosurgical Unit and Accessories  
Classification name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

B. *Predicate devices*

<u>Device</u>	<u>Premarket Notification</u>
ArthroCare Arthroscopic Electrosurgery System	K943450
ArthroCare Dental Electrosurgery System	K962445
ArthroCare Bipolar Loop Electrosurgery System	K955531
ArthroCare Urologic Multi-electrode Electrosurgery System	K961069
ConMed Hyfrecator Plus	K800617

C. *Device description*

The ArthroCare Dermal Electrosurgery System is comprised of three components: the Dermal Handpiece with Cable unit, the disposable Dermal Handpiece Tip, and an electrosurgical generator called the Controller. The Dermal Handpiece Tip attaches to the distal end of the Dermal Handpiece and Cable. The proximal end of the Dermal Handpiece and Cable unit connects to the Controller. The Dermal Handpiece Tip is provided in a variety of models, ranging in diameters from 0.5 mm to 2.5 mm with the distal tip of the dermal Handpiece as straight or bent at angles up to 90 degrees. The distal tip is configured with multi-electrodes. The Dermal Handpiece Tip is supplied sterile and intended for single patient use. The Dermal Handpiece and Cable unit are designed for repeat sterilization by either ethylene oxide gas or steam autoclaving methods. The Controller is a high frequency electronic instrument. There is no software utilized in the operation of the Controller.

The ArthroCare Dermal Electrosurgery System 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 Dermal Electrosurgery System and ConMed Hyfrecator are intended for use in dermatologic surgical procedures to remove soft tissue and to control bleeding.

*E. Technological characteristics*

The technological characteristics of the ArthroCare Dermal Electrosurgery System are the same as those of the ConMed Hyfrecator Plus as well as the ArthroCare Arthroscopic System, Bipolar Loop, Dental, and Urologic Multi-electrode Systems. These devices are equivalent in terms of materials, principle of operation and sterilization.

*F. Summary*

By virtue of design, principle of operation, materials and intended use, we believe the ArthroCare Dermal Electrosurgery System is substantially equivalent to devices currently marketed in the United States. We believe that the ArthroCare Dermatologic Electrosurgery System, which is intended for removal of dermatologic lesions and hemostasis in dermatologic surgical procedures, does not raise any new issues of safety and/or effectiveness.