

DeRoyal Industries, Inc.
Electrosurgical Cautery Pencil Adapters

K961087

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED

MAY 16 1996

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc. TELEPHONE: (423) 938-7828
ADDRESS: 200 DeBusk Lane CONTACT: Debra F. Manning
Powell, TN 37849 DATE OF PREPARATION: March 18, 1996

DEVICE NAMES

NAME: DeRoyal Surgical (SurgiMate) Electrosurgical Cautery Pencil Adapters
COMMON/USUAL NAME: Electrosurgical Cautery Pencil Adapters
CLASSIFICATION NAME (if known): Electrosurgical Cutting & Coagulation Device & Accessories

PREDICATE OR LEGALLY MARKETED DEVICES

ValleyLab
Weck

DEVICE DESCRIPTION

The DeRoyal Surgical Electrosurgical Cautery Pencil Adapter functions in the same manner as predicate devices in that it is used to connect one type of electrosurgical Cautery Pencil to a particular type of jack on the electrosurgical cautery machine being used.

Device Design/Materials Used/Physical Properties: The DeRoyal Cautery Pencil Adapter is made of materials commonly used for its purpose. The concept of use is that the adapter converts one type of connection to another type of connection without any alteration of the circuit or any impact on the performance of the original circuit.

DEVICE INTENDED USE

The DeRoyal Cautery Pencil Adapter is indicated for use whenever the ESU machine requires a Cautery Pencil of the type provided by SurgiMate, or the connector on the SurgiMate Pencil does not match the intended jack of the ESU machine but its use would make the electrical connection compatible.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Input Connector	Proprietary cautery pencil connector	Same
Output Connector	Target machine connector	Same
Sterility	Non-sterile	Same
Circuit	Direct wiring from input connector to output connector	Same