§ 884.4160 Unipolar endoscopic coagulator-cutter and accessories.

(a) Identification. A unipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.

(b) Classification. Class II. The special controls for this device are:


(ii) “510(k) Sterility Review Guidance 2/12/90 (K-90),” and

(iii) “Guidance (‘Guidelines’) for Evaluation of Hysteroscopic Bipolar and Bipolar Thermal Coagulators (and Accessories).”


(3) American National Standards Institute/American Association for Medical Instrumentation’s HF–18, 1993, “Electrosurgical Devices,”

(4) Labeling:

(i) Indication: For female tubal sterilization, and

(ii) Instructions for use:

(A) Destroy at least 2 centimeters of the fallopian tubes,

(B) Use a cut or undampened sinusoidal waveform,

(C) Use a minimum power of 25 watts, and

(D) For devices with ammeters: continue electrode activation for 5 seconds after the visual endpoint (tissue blanching) is reached or current flow ceases indicating adequate tissue destruction.