§ 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 ground 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.

(ii) “510(k) Sterility Review Guidance 2/12/90 (K–90),” and
(iii) “Guidance (‘Guidelines’) for Evaluation of Laproscopic Bipolar and 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.