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SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE TRIGGER SWITCH AND CORD

K970140

The Trigger Switch and Cord accessories are intended for use in monopolar laparoscopic and thoracoscopic electrosurgical procedures where handswitching of laparoscopic or thoracoscopic instruments, such as scissors and graspers, is desired.

The Trigger laparoscopic switch system consists of a sterile, single use switch and a sterile single use cord that is used to deliver monopolar RF current from a standard electrosurgical generator to a laparoscopic or thoracoscopic instrument.

The switch contains a female electrical connector that mates with the electrosurgical connector post on a laparoscopic or thoracoscopic instrument and a male connector that mates with the power cord. The adhesive on the switch button allows it to be placed on the instrument in a user-selected location. When the switch assembly is connected via the power cord to an electrosurgical generator, depression of the switch button results in the activation of the coagulation output of the generator.

The Trigger Switch and Cord are non-patient contact accessories, thus, biocompatibility testing is not pertinent.

The Trigger Switch and Cord have been tested in accordance with the following standards:

- IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 601-2-2 (1991), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment
- ANSI/AAMI HF18 (1993), Electrosurgical Devices

The Trigger Switch and Cord accessories are substantially equivalent in function and intended use to the following legally marketed devices: E2750, Laparoscopic Pencil Grip Handset (K904560); E2751, Laparoscopic Pistol Grip Handset (K925647); and E0510 Laparoscopic Cord (Preamendments Device).

The Trigger Switch and Cord are substantially equivalent to the above devices in that all of the devices are accessories which are used to deliver RF current from a standard electrosurgical generator to the surgical site during laparoscopic or thoracoscopic procedures. Both the trigger switch and the laparoscopic handsets provide a switching mechanism for output control.