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510(k) Summary
I.C. Medical Telescoping PenEvac

K 955166

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NEW Trade Name

Device Trade Name: PenEvac SI

Common Name: Electrosurgery, Suction & Irrigation Handpiece with Smoke Evacuation Tube, Telescoping Tip and Monopolar Electrodes.

Classification Name: Unknown

Substantial equivalence to the following:
1. Telescoping PenEvac (I.C. Medical)
2. Disposable Laparoscopic Handswitch. (Valleylab)

Description of the PenEvac SI:

The predicate device (Telescoping PenEvac) was modified by adding an irrigation channel to create the PenEvac SI. The modification required moving the suction/irrigation ports to an adapter at the front of the device and using an "end cap" when the smoke evacuation tubing is not used. The Valleylab Disposable Laparoscopic Handswitch was added as a predicate device only because it includes all three functions (monopolar electrosurgery, suction, & irrigation).

The PenEvac SI is a multifunction device that optionally features suction, irrigation, electrosurgery "cut" or "coag," and smoke evacuator functions. The device is intended to be used with an I.C. Medical Suction/Irrigator/Smoke Evacuator and common electrosurgery generators.

The PenEvac SI has a handpiece body that accepts various tips and endpieces to furnish different operating functions. The handpiece body will be available as either a sterile single use device or as a reusable device. The handpiece features two pushbutton switches and an electrosurgery cord and connector. The handpiece bodies are identical to the predicate Telescoping PenEvac bodies.

Changing the tip will change the function of the handpiece. There are three different configurations available:

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SIE (Suction, Irrigation, monopolar Electrode) Configuration: Three components replace the telescoping tip on the PenEvac body. A (1) Suction/Irrigation Tip is attached to the (2) Suction Irrigation Adapter. Then the electrode on the end of the (3) ESU Electrode Adapter is inserted through the irrigation channel on the Suction/Irrigation Tip until the ESU Adapter is completely threaded onto the Tip. Both of these parts are then threaded onto the front of the PenEvac Body in place of the Telescoping Tip. Suction and irrigation tubing is then connected to the short pieces of tubing attached to the Suction/Irrigation Adapter. An endcap replaces the smoke evacuator tubing that is used with the Telescoping PenEvac. The ESU Electrode Adapter is available with the same types of electrodes available with the predicate Telescoping PenEvac.

In this configuration (SIE) suction, irrigation, and monopolar electrode functions are available whenever the surgeon desires them. Smoke is evacuated through the suction channel.

SI (Suction, Irrigation) 2 Channel: All components are the same as the SIE configuration except the ESU Electrode Adapter is not used. Instead, the Suction Irrigation Adapter is directly attached to the PenEvac Body and the Suction Irrigation Tip is attached to the Adapter.

In this configuration (SI) suction and irrigation are available and they can be made to occur simultaneously as the surgeon desires.

SI (Suction, Irrigation) 1 Channel: The components are the same as in the SI configuration except the 2 channel tip is replaced with a single channel tip. This is an economy set up for surgeons who do not need simultaneous suction and irrigation functions.

Plastic and metal materials used in the PenEvac SI are identical to those used in the predicate Telescoping PenEvac with the exception of one type of tubing that has been Class VI certified.

Intended Use of the PenEvac SI:

The PenEvac SI is a multifunction handpiece that is meant to provide the following optional functions: monopolar electrode handpiece in an electrosurgery generator system, suction, irrigation, and to facilitate the removal of smoke generated during the procedure. The intended use is the same as the predicate devices.

**Summary of Technological Characteristics:
PenEvac SI/Predicate Device(s)**

The PenEvac SI is multifunction handpiece with the following uses: suction, irrigation, monopolar electrosurgery "cut" or "coag", smoke evacuation. The Telescoping PenEvac by I.C. Medical, Inc. is the predicate device for the telescoping tip, monopolar electrosurgery, and smoke evacuation (suction) features. The Valleylab Disposable Laproscopic Handswitch handpiece is the predicate device for combining the electrosurgery and suction functions with irrigation in the same handpiece.

The PenEvac SI consists of a handpiece body, interchangeable tips, and interchangeable endpieces. The handpiece bodies will be available as sterile single use items and also as reusable items.

The sterile disposable products will be sent to the same contract sterilizer who currently provides that function for the I.C. Medical Telescoping PenEvac and ESU shrouds. The sterilization validation method has been reviewed

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and accepted by the FDA during a recent (June 1995) site inspection. The Sterility Assurance Level and the ETO Residual Level will be the same as the predicate ESU shrouds.

The reusable PenEvac SI body (includes: ESU shroud/handswitching pencil body, three conductor cord, & connector; does not include: telescope tip, electrode, smoke evacuator tube, suction tube, or irrigation tube) may be sterilized by ETO, steam, steris, or flash autoclave up to 134 degrees centigrade. It may be reused until it fails a continuity check or shows signs of wear, damage, cracking, or chipping.

The predicate Telescoping PenEvac uses a single tip that telescopes to the length desired by the surgeon and the PenEvac SI uses tips with fixed lengths to accommodate the surgeon. The PenEvac SI smoke evacuator/pencil body will be molded from the same material as the predicate Telescoping PenEvac. The smoke evacuator tubing and connectors are identical to the predicate device.

The predicate electrosurgical pencil features optional electrodes of different lengths and shapes. The PenEvac SI has similar optional electrode shapes. Both pencils use the same electrode material.

The PenEvac SI and the predicate Telescoping PenEvac are handswitching monopolar devices. They both have "cut" and a "coag" pushbuttons and are made of the same materials. The connectors on both devices fit common electrosurgery generators and the connecting cables are ten foot, flexible, three conductor products.

The electrical cord, generator connector, and switches (cut & coag) are the same for the PenEvac SI and Telescoping PenEvac.

The specifications of the PenEvac SI are comparable to the predicate I.C. Medical Telescoping PenEvac and Valleylab Disposable Laparoscopic Handswitches.

I.C. Medical feels that the Telescoping PenEvac SI functions the same as the predicate devices and we have not identified any significant changes in safety and effectiveness.

Summary of Nonclinical Tests & How Results Support Equivalence:

Samples of all proposed tip materials have been tested for flammability when used with various electrosurgery generators and all have passed the same tests that were applied to the Lexan polycarbonate used with the predicate ESU shroud.

The PenEvac SI was also bench tested with a number of different electrosurgery generators and the smoke evacuation and electrocautery pencil functions of the PenEvac SI were the same as the predicate ESU shroud and pencils.

The Chief Engineer and/or the manufacturer of the cable/connector/switches tested the prototype devices and they comply with the applicable portions of ANSI/AAMI HF-18: 1993 Electrosurgical Device standard. Validation will also be performed on production devices prior to their initial release for compliance to the standard.

Relative capacitive resistance between the PenEvac SI and the predicate Valleylab laparoscopic devices was evaluated by measuring current flow from the device under test to the ground pad in a simulation of normal use conditions. It was concluded that both of the laparoscopic devices have virtually identical capacitive resistance.

END OF 510(K) SUMMARY