

K961616

510(k) Summary
I.C. Medical Telescoping PenEvac (Modification)
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MAY 28 1996

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	Date Summary Was Prepared:	May 7, 1996
Device	Trade Name:	Telescoping PenEvac
	Common Name:	Electrosurgery Pencil with Smoke Evacuation Tube and Telescoping Tip, and electrodes
	Classification Name:	GEI: Device, Electrosurgical, Cutting & Coagulating, & Accessories
	Substantial equivalence to the following:	1. Valleylab Disposable Handswitching Pencil 2. Valleylab Reusable Handswitchingencil 3. I.C. Medical Electrocautery Shroud

This submission is the same as a previously submitted 510(k) application (k954088) that was found substantially equivalent with the following exceptions:

- An additional material is being added to the list of materials that may be used to mold the Reusable PenEvac Body;*
- Biocompatibility and sterilization compatability information for the material that will be used on reusable products only has been added and sterilization information on disposable products has been eliminated.*

Description of Telescoping PenEvac:

The Telescoping PenEvac is a combination of an electrosurgery switching handpiece and a smoke evacuation shroud with a telescoping tip that allows the surgeon to adjust the tip length. It includes pushbutton switches to allow the surgeon to select "cut" or "coagulation" operating modes on typical electrosurgery generators.

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The device will be marketed in two versions:

One: As a complete single use sterile product.

Two: As a partially reusable product with the PenEvac body and electrosurgery cord being reusable and the remainder of the device as a sterile single use product.

Electrodes of various lengths and shapes will be available.

Intended Use of the Telescoping PenEvac:

The Telescoping PenEvac is intended to be used as the active monopolar electrode in an electrosurgery generator system and to facilitate the removal of smoke that is generated during the procedure.

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

The PenEvac is a combination smoke evacuator and electrocautery handswitching pencil. The smoke evacuator portion is being compared to the I.C. Medical ESU shroud and the electrocautery pencil portion is being compared to the ValleyLab Disposable Handswitching Pencil and the ValleyLab Reusable Handswitching Pencil. The PenEvac will be marketed in two ways: a) as a completely disposable product b) as a partially reusable product (the PenEvac body with handswitches, ESU cord, and connector) with disposable sterile accessories.

The reusable PenEvac body (includes: ESU shroud/handswitching pencil body, three conductor cord, & connector; does not include: telescope tip/electrode, or smoke evacuator 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.

An additional material is being added to the list of materials that the reusable PenEvac body may be molded from. Biocompatibility and sterilization data is included in the 510(k) application. The addition of this material does not change any sterilization or use parameters.

The predicate ESU shroud has optional tips of various lengths to accommodate different pencil electrode lengths of the predicate electrosurgical pencil. The PenEvac uses a single tip that telescopes to the length desired by the surgeon. The PenEvac smoke evacuator/pencil body will be molded from the same material as the predicate ESU shroud or from other plastic resins that are on file with the FDA. 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 also has optional electrode shapes.

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The PenEvac and the predicate electrosurgery pencils are handswitching monopolar devices. The PenEvac has a "cut" and a "coag" pushbutton as do the predicate pencils. The PenEvac electrode is made of materials that are commonly used on surgical devices. The connector fits common electrosurgery generators and the connecting cable is a ten foot, flexible, three conductor product as are the predicate pencils.

The electrical cord, generator connector, and switches (cut & coag) are being purchased from a manufacturer that supplies these items to other electrosurgical handpiece manufacturers for use in their devices.

The specifications of the PenEvac are comparable to the predicate I.C. Medical ESU Shroud and Valleylab electrosurgery handpieces.

I.C. Medical feels that the Telescoping PenEvac 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 was also bench tested with a number of different electrosurgery generators and the smoke evacuation and electrocautery pencil functions of the PenEvac 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.

Test data on the material added for the reusable PenEvac body indicate that the material is USP Class VI certified and that the material is compatible with the sterilization parameters.

END OF 510(K) SUMMARY

**Information beyond this statement is
NOT part of the 510(k) Summary**