K955020

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510(k) Summary of Safety & Effectiveness As Required by 21CFR807.92

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	Date Summary Was Prepared: **Date Summary Was Amended:** **Date Summary Was Amended:**	October 25, 1995 February 8, 1996 March 15, 1996
Device	**Trade Name:**	Telescoping PenEvac ABC
	Common Name:	Argon Beam Coagulator/Electrosurgery Pencil with Smoke Evacuation Tube, Telescoping Tip, and electrode.
	Classification Name:	Electrosurgical Device Cutting & Coagulation Accessory (79GEI)
	Substantial equivalence to the following:	1. I.C. Medical Telescoping PenEvac 2. Valleylab "Force GSU handset" E2522H

Description of Telescoping PenEvac ABC Handpiece:

The Telescoping PenEvac ABC is a combination of an argon beam coagulator pencil and an electrosurgery switching handpiece with a smoke evacuation shroud. It is intended to be used with argon beam generators that include electrosurgery capabilities. The device has push button switches to allow the surgeon to select CUT, COAG, or ARGON functions on the generator. An ARGON ASSIST mode can be selected by sliding the tip of the ABC Telescoping Tip back to expose the monopolar electrode.

The device consists of three major components: PenEvac Body, ABC Adapter, and ABC Telescoping Tip. The PenEvac Body contains the pushbutton switches and ESU cord and connector. The ABC Adapter fits into the rear of the PenEvac Body and contains flexible tubing, generator connector, electrical conductor, and a rigid metal tube that fits into the PenEvac Body. The ABC Telescoping Tip is used during open surgical procedures. The tip may be extended or shortened as desired. It also has a sliding tip that can expose, or conceal, the electrode during argon procedures.

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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 ABC Adapter being reusable and the remainder of the device as a sterile single use product.

The device will also be marketed with two different types of argon beam generator connectors. One will be compatible with Valleylab argon beam coagulator systems and the other with Birtcher argon beam coagulator systems.

Intended Use of the Telescoping PenEvac ABC Handpiece:

The Telescoping PenEvac ABC is intended to be used only during open surgical procedures as the active handpiece in a combination argon beam coagulator/electrosurgery generator system that uses monopolar electrodes and to facilitate the removal of smoke that is generated.

Summary of Technological Characteristics:
Telescoping PenEvac ABC Handpiece/Predicate Device(s)

The Telescoping PenEvac ABC Handpiece is a combination smoke evacuator, electrocautery handswitching pencil, and an argon beam coagulator handpiece. The smoke evacuator and electrosurgery portions are being compared to the I.C. Medical Telescoping PenEvac (K954088) and the argon beam coagulator handpiece portion is being compared to the ValleyLab Force GSU Handset (catalog number E2522H). The Telescoping PenEvac ABC will be marketed in two ways: a) as a completely disposable product b) as a partially reusable product (the PenEvac body with switches, ESU cord, and connector) with disposable sterile accessories. It will also be available with electrical and gas connector plugs to fit Valleylab or Birtcher type argon beam delivery systems.

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

The reusable PenEvac Body and ABC Adapter 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 Telescoping PenEvac and Telescoping PenEvac ABC feature a monopolar electrode that telescopes along with the smoke evacuator tube to the length desired by the surgeon. Telescoping PenEvac ABC and the Force GSU handset both have telescoping electrodes and a gas delivery system that allows argon to flow along both sides of the electrode. The Telescoping PenEvac ABC and Force GSU both have operating controls that allow selection of the following modes of operation: electrosurgery "cut", electrosurgery "coag", argon beam only, argon assisted.

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The Telescoping PenEvac ABC, Telescoping PenEvac, and Force GSU handpieces are handswitching monopolar electrosurgery devices. The Telescoping PenEvac ABC and Force GSU also may deliver argon coagulation beams. 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 Telescoping PenEvac ABC will be available with an argon gas tube connector that is compatible with Valleylab Force GSU argon beam coagulation devices and it will also be available with a connector that fits Birtcher argon beam units.

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

The specifications of the Telescoping PenEvac ABC are comparable to the predicate I.C. Medical Telescoping PenEvac and Valleylab Force GSU handpieces.

I.C. Medical feels that the Telescoping PenEvac ABC 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 Telescoping PenEvac.

The Telescoping PenEvac ABC was also bench tested with a number of different electrosurgery generators and an argon beam coagulator. The smoke evacuation, electrocautery pencil, and argon beam coagulator functions of the Telescoping PenEvac ABC were essentially the same as the predicate Telescoping PenEvac handpiece and the Force GSU handpiece.

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.

END OF 510(K) SUMMARY

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