510(k) Summary of Safety & Effective
as required by 21CFR807.92
I.C. Medical SI Controller

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K960492

510(k) Summary

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	Device Trade Name:	SI Controller, Model SI 500
	Common Name:	Irrigation, Aspiration, Hydro-Dissection System and Accessories
	Classification Name:	BTA: Powered Suction Pump (878.4780)
	Substantial equivalence to the following: SI Controller:	Cabot Medical, Cabot Irrigation Pump; Nezhat-Dorsey Hydro-Dissection System; ~~Bard/Davol, Endo-Flo Irrigation System~~
	Tubing Sets:	I.C. Medical Sterile Disposable Tubing Set (p/o K932230) I.C. Medical PenEvac SI (K955166)

Description of the Suction/Irrigation Controller:

The SI Controller Model SI500 controls the flow of fluids and vacuum to suction/irrigation and multifunction accessories used during ~~wound care and~~ open and closed surgical procedures and may be used for hydro-dissection. Also included in this 510(k) application are tubing sets, disposable fluid canisters and accessories used

to connect other surgical accessories to the irrigation fluid and vacuum sources. An electrical cable is also provided to accommodate remote sensing from I.C. Medical Crystal Vision smoke evacuators (K932230) in order to automatically activate and deactivate the SI Controller. I.C. Medical recommends that this device be used with the PenEvac SI (K95166) which is a multifunction suction, irrigation, ESU monopolar electrode device.

Except for comparison of tubing sets, the Crystal Vision (K932230) smoke evacuator is not part of this 510(k) application and its mention is only for clarity in the function of the SI Controller. The Crystal Vision smoke evacuator has a remote sensor that is used to sense the activation of an ESU generator. The remote sensor has no electrical connections to the generator. When generator activation is sensed, the smoke evacuator pump is started and vacuum is present at the input filter of the evacuator. This vacuum source may be optionally used, instead of wall suction, with the SI Controller. A cable is provided from the smoke evacuator to the SI Controller to sense activation of the smoke evacuator. SI Controller activity at that time depends on the mode selected as described later.

The PenEvac SI (K955166) is a multifunction device that can provide, depending on tip selection, suction, irrigation, and ESU monopolar electrode functions. The materials used in the fluid and suction channels (tubing, connectors, and plastic resins) of the PenEvac SI are being used as a predicate for the tubing sets included in this 510(k) application along with the materials used in the Sterile Disposable Tubing Set (p/o K932230).

The description of the SI Controller is divided into three sections: irrigation, suction, and activation.

Irrigation Section:

The irrigation section includes a peristaltic pump. Irrigation tubing is routed from two irrigation bags, through two flow control solenoids, into a fluid sensor, through the pump (in all modes except AUTO ~~3CF~~) and then to the PenEvac SI device. A heat retaining plate is positioned between the two irrigation bags. Flow and pressure adjustments are available.

When the controller senses a request for irrigation fluid, one of the bags is automatically selected and a solenoid opens to allow fluid to flow. If no fluid is sensed by the Fluid Sensor, the first solenoid is closed and the second bag is selected by automatically opening the other solenoid.

The heat retaining plate is not capable of warming large volumes of fluid, it is intended simply to minimize heat loss while the bags are exposed. The maximum temperature of the plate is 30 decrees centigrade.

There are also push buttons that open the flow solenoids so that the irrigation tubing may be inserted and a push button that turns the pump on so that the irrigation tubing can be filled with fluid and purged of air.

Suction Section:

Vacuum may be provided from either wall suction or from a Crystal Vision smoke evacuator. There is a switch to select the vacuum source.

WALL SUCTION: Tubing connects the wall suction outlet to the back of the SI Controller and then from the front of the controller to a disposable fluid canister. Sterile tubing is then used to connect the fluid canister to the PenEvac SI device. When wall suction is used, flow can be controlled from the front panel of the SI Controller.

SMOKE EVACUATOR SUCTION: Tubing connects the input filter of the smoke evacuator to the fluid canister, and then sterile tubing is used to connect the canister to the PenEvac SI. Flow is controlled by the FLOW control on the Crystal Vision smoke evacuator.

Activation Section:

There are four activation modes available with the SI Controller. The MANUAL MODE is used with accessories that provide only suction and irrigation functions and the surgeon must activate the control on the accessory to activate/deactivate suction and irrigation . The other modes of operation provide automatic activation/deactivation when deactivation of an ESU generator is sensed.

MANUAL MODE: The manual mode is used with a PenEvac SI accessory that does not provide an electrocautery monopolar electrode function. The surgeon can select suction, or irrigation , or simultaneous suction/irrigation (depending on the tip used) by depressing the appropriate button on the PenEvac SI body.

AUTO 1 MODE: This mode provides for simultaneous suction and irrigation when the ESU generator is deactivated. Upon generator deactivation, the irrigation runs for an adjustable amount of time and then it automatically deactivates. Suction continues for an amount of time after irrigation deactivates and then it also stops.

AUTO 2 MODE: Irrigation is provided automatically for an adjustable amount of time when ESU generator deactivation is sensed. Upon cessation of irrigation, suction automatically is provided for an adjustable amount of time.

AUTO 3~~CT~~ MODE: The pump is not activated in this mode. Upon sensing ESU activation, the appropriate flow control solenoid opens and allows gravity fed fluids to flow. Suction commences automatically.

~~OPTIONS: Two options will be available with the SI Controller.~~

The following circuits effect the SI Controller activation in all modes:

OVER PRESSURE: The over pressure circuit monitors the pressure in the suction line when suction is not activated. This is useful during closed procedures. If the pressure exceeds the set value, the suction is activated to reduce the pressure.

OCCLUSION: The suction circuit monitors the vacuum in the suction line while the suction circuit is activated. If an occlusion is detected. The suction is deactivated. This option is useful to prevent tissue trapping.

Accessories:

Irrigation Tubing: This sterile set provides connection of two typical irrigation bags to the suction/irrigation device. It has two beveled edged connectors for easy insertion into the irrigation bag connection. It also has tubing sections compatible with the fluid flow sensor and peristaltic pump. The distal connector is compatible with the PenEvac SI multifunction accessories.

Suction Tubing (PenEvac SI to suction canister): This is a sterile tubing set. Its connections are compatible with the PenEvac SI device and common suction canister.

Suction Tubing (other): Various lengths of non-sterile tubing are available for inter-connecting the suction canister with either a Crystal Vision smoke evacuator or with typical wall suction connectors.

Electrical cable: A two conductor electrical cable is used to connect the SI Controller to Crystal Vision smoke evacuators.

ESU Sensor (part of K932230): This sensor can be connected directly to the SI Controller if wall suction is used as a vacuum source instead of a Crystal Vision smoke evacuator.

Intended Use of the Suction/Irrigation Controller:

The I.C. Medical SI Controller Model SI 500 is intended to be used to control the flow of irrigation fluids and vacuum to suction/irrigation and multifunction accessories having compatible suction/irrigation features during ~~wound care and~~ open and closed surgical procedures. When used with appropriate accessories the SI Controller may be used for hydro-dissection.

The SI Controller is not intended for use in delivering any blood or blood products

Summary of Technological Characteristics:

The SI Controller uses a peristaltic pump, fluid sensor, and solenoids to control the flow of irrigation fluids. The pump can deliver continuously variable flows from 0-3.5 gpm. Pressure may also be varied within a pressure

range that is comparable to other devices used during laparoscopic procedures. The electrical specifications are the same as other electrical devices used in the operating room.

The SI Controller has a temperature controlled heat retaining plate that is meant to minimize heat losses from previously warmed bags of irrigation fluids. The heat retaining plate is not meant to heat cold bags of fluids and it has a maximum temperature of 38 degrees centigrade.

The tubing sets will be packaged and sterilized in the same manner as the predicate tubing sets. The materials used in the tubing sets are the same, with the exception of the peristaltic pump tubing, as those used in the predicate devices. The peristaltic pump tubing is suitable for use in these tubing sets.

I.C. Medical has concluded that the SI Controller and its tubing sets are substantially equivalent to the predicate devices.

END OF 510(K) SUMMARY

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