

K964621

DEC 20 1996

**510(K) SUMMARY FOR A&E MEDICAL ELECTROCAUTERY
SUCTION TUBE WITH FINGER TIP ACTIVATOR BUTTON
(AS REQUIRED BY 21 CFR 807.92c and SMDA 1990)**

SUBMITTER: ALTO DEVELOPMENT CORPORATION
5206 ASBURY ROAD
FARMINGDALE, NJ 07727

908-938-2266
908-938-2399 FAX

CONTACT: MICHAEL T WOJCIECHOWICZ
DATE: NOVEMBER 12, 1996 (Amended 11/27/96, 12/3/96, 12/12/96)

510(K) SUMMARY

TRADE NAME: A&E MEDICAL FTC ELECTROCAUTERY
SUCTION TUBE WITH FINGER TIP ACTIVATION
SWITCH

COMMON NAME: FINGER TIP CONTROL ELECTROCAUTERY
SUCTION TUBE

CLASSIFICATION NAME: ELECTROSURGICAL, CUTTING &
COAGULATION & ACCESSORIES
(PER 21 CFR 878.4400)

EQUIVALENT DEVICES:

1. VALLEYLAB ELECTROVAC II MODEL E2610-6
MARKETED BY VALLEYLAB INC, BOULDER, CO

2. A&E MEDICAL ELECTROCAUTERY SUCTION TUBE MODEL 050-005
MARKETED BY ALTO DEVELOPMENT CORPORATION,
FARMINGDALE, NJ

DEVICE DESCRIPTION: The monopolar electrosurgical device consists of an electrically conducting cannula which has plastic electrical insulation on its exterior surface. This cannula fits into a plastic handle that has a central axial passage in line with the suction hole of the cannula. This suction hole leads to a suction hose fitting molded into the aft end of the handle. During use a hose connected to an external suction source is connected to the handle's suction fitting to provide suction to the cannula. A bleed hole in the handle allows the surgeon to control the amount of suction with his fingertip. High frequency power is supplied to the device through a 10 foot long power cord which enters the aft end of the handle and is internally connected to the cannula and switching circuitry. The distal end of the power cord has a standard plug that fits into most electrosurgical generators that have the accessory fingertip control option. The surgeon activates the cautery tip by pressing a push button located near the suction bleed hole.

The new device will be marketed in cannula french size 10 with a 6 inch length

INTENDED USE: For use with electrosurgical generators that have the accessory finger tip activation feature to control bleeding through the use of suction and cautery.

510(K) SUMMARY

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICES:

<u>Similarities/ Differences</u> (Differences in Bold Type)	<u>510(K) Device</u>	<u>VL E2610-6</u>	<u>A&E 050-005</u>
1. Cannula size/length	10 French,6 inches	10 French, 6 inches	10 French, 6 inches
2. Cannula insulation material..	Polyolefin/.025 in.	Polyolefin/.025 in.	Polyolefin/ .025 in.
3. Cannula tube material.....	Brass	ALUMINUM	Brass
3. Suction bleed control vent	Yes, .120x.250 in.	Yes, .115x.350 in.	Yes, .120x.250 in
4. Suction port size	1/4" tubing	1/4" tubing	1/4" tubing
5. In handle, suction vent isolated from fluid path	Yes	Yes	Yes
6. Handle material	Polystyrene	Polystyrene	Polystyrene
7. Wire cord insulation	PVC	POLYOLEFIN	PVC
8. Wire terminal(ESU connector) ..	Standard .125 dia.	Standard .125 dia.	Standard .125 dia.
9. Energy source (Monopolar ESU)	Yes	Yes	Yes
10. Electrode tip design060 in. bare tip	.120 in. bare tip	.060 in. bare tip
11. Mode of operation.....	Push button activation	Push button activation	foot petal activation
12.Push button location	Near bleed hole	Near bleed hole	NONE
13.Push button circuitry		Identical to 510(K)	NONE
14.Indications		Identical to 510(K)	Identical to 510(K)
15. Insulating Materials		SEE ITEM 7	Identical to 510(K)
16.Overall length	10.75 in.	10 in.	10.75 in.
17.Electrosurgical effect		Identical to 510(K)	Identical to 510(K)
18.Cleaning Stylet070 dia./polystyrene	.078 Dia/unknown	.070 dia./polystyrene

SAFETY AND EFFECTIVENESS STATEMENT FOR ELECTROSURGICAL DEVICES

The effectiveness and safety of electrosurgery as a cutting and coagulation method is extensively documented and well known. The hazards of electrosurgery are similarly well known and documented. The attached bibliography provides in depth information regarding the safety, effectiveness and hazards of electrosurgery.

Generally the hazards can be identified as patient /user burns or electrical interference with an electric device such an implanted pacemaker. In addition, as electrosurgery creates a spark, flammable gases or materials could ignite.

Overwhelmingly, the majority of burns are a result of a ground fault in the patient/dispersive electrode/generator return current pathway. As the current finds an alternate path to ground (through the table, ECG lead, towel clip, etc.), it concentrates at this area causing a burn. the severity of the burn depends upon the time of exposure to the current. Improper attachment of

510(K) SUMMARY

the dispersive electrode to the patient is the most common cause of ground fault burns. Additionally, these types of burns can also occur from a defective return circuit in the generator, a defective dispersive electrode, or user error in the system set up. The subject product of this 510(K) notification can not contribute to ground fault type burns.

Less frequently, burns occur as a result of an activated active electrode contacting electrically conductive instruments of equipment. In these cases, the electrosurgical effect is transmitted along the conductive pathway to unintended locations. Even though the active electrode is involved in these instances, contact with the instruments or equipment is required. This contact occurs accidentally by the user and is not device related.

The current interference with electronic equipment occurs when the dispersive electrode is positioned in such a way that the current pathway through the patient crosses over the equipment. Placing the dispersive electrode in a location which prevents the current flow from crossing over the electronic equipment will avoid the interference. the dispersive electrode placement is totally user dependent and unrelated to the subject device.

Specific hazards associated with the subject 510(K) device would involve insufficient materials and design to safely carry the current without leakage or switch anomalies could cause unintended activation of the current. However, as electrosurgery is so common, an industry standard has been developed to ensure the safety of all components of a electrosurgical system. This Standard, ANSI/AAMI HF18-1993 defines the parameters, tests and requirements needed to assure the safety of electrosurgical system components. The subject device of this 510(K) notification meets all applicable requirements of this standard.

510(K) SUMMARY

BIBLIOGRAPHY OF ARTICLES SUPPORTING THE SAFETY AND EFFECTIVENESS OF ELECTROSURGERY

- 1) Church & Hamlin, Electrosurgery Demands or Vigilance, AORN Journal, Dec. 1975, Vol. 22, No 6.
- 2) Boughton & Spencer, Electrosurgical Fundamentals, Journal American Academy Dermatology, 1987, Vol 16, pgs. 862 to 867.
- 3) Moak, Electrosurgical Unit Safety, AORN Journal, March 1991, Vol.53, No. 6.
- 4) Neufeld, Principles & Hazards of electrosurgery Including Laparoscopy, Surgery, Gynecology & Obstetrics, Nov. 1978. Vol. 147.
- 5) Recommended Practices - Electrosurgery, AORN Journal, April 1991, Vol. 53, No. 4.
- 6) Emergency Care Research Institute, Electrosurgical Units, Technology for Surgery, Nov, 1987, Vol. 8.
- 7) Schellhammer, Electrosurgery: Principles, Hazards, & Precautions, Urology, Mar. 1974, Vol. 3.
- 8) Emergency Care Research Institute, Update: Controlling the Risks of Electrosurgery, Technology For Surgery, Jan. 1990, Vol. 10.
- 9) Oearce, Current Electrosurgical Practice: Hazards, Journal of Medical Engineering and Technology, Jan 1990, Vol 10.
- 10) Sebben, Electrosurgery & Cardiac Pacemakers, Journal American Academy Dermatology, 1983, Vol, 9.
- 11) Battig, Electrosurgical Burn Injuries and Their Prevention, Journal American Medical Association, June 1968, Vol. 204