

K955282

TAB G
SUMMARY OF SAFETY AND EFFECTIVENESS

1056

Device Name:

Classification Name: Liquid Medication Dispensers: 21CFR 880.6430, Class I

Common/Usual Names: Syringe, Applicator, Dispenser

Proprietary Names: ThermoGenesis Applicator
ThermoGenesis Applicator Kits
ThermoGenesis Applicator Tips
ThermoGenesis Spray Applicator

Device Sponsor: ThermoGenesis Corporation
11431 Sunrise Gold Circle, Suite A
Rancho Cordova, CA 95742

Regulatory Classification: Class I

Summary of Safety and Effectiveness:

ThermoGenesis Applicators and Applicator Tips are intended to deliver two solutions simultaneously to a medical or surgical site. These products are supplied sterile and are intended for single patient use.

The ThermoGenesis Applicator product line consists of two devices: (1) a drop applicator with various straight, angled and flexible dual cannulated applicator tips, and (2) a spray application device with tip. All configurations of these products allow the user to deliver two solutions using one hand. All configurations of the devices are only intended for simultaneous application of two solutions and are specifically not intended for intravenous injection.

ThermoGenesis Applicator products are substantially equivalent in design, function and materials to other liquid medication dispensers being distributed by companies like Hemaedics and Micromedics. These products utilize commonly available blunt syringes and hypodermic needles, and therefore, do not raise any new safety or effectiveness issues when compared to similar devices.

109