



The New Marq of Excellence

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K962220

**Non-Confidential Summary of Safety and Effectiveness  
June 3, 1996**

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Marquest Medical Products, Inc.  
11039 East Lansing Circle  
Englewood, CO 80112

Tel - (303) 790-4835  
Fax - (303) 799-0210

**Official contact:** Tom Dielmann, Director, Regulatory Affairs / Quality Assurance

**Proprietary or Trade Name:** Heated wire breathing circuits and limbs

**Common/Usual Name:** Heated wire breathing circuits and limbs

**Classification Name:** 73 BZE - Breathing systems heater w/wo controller  
(not humidifier or nebulizer)  
Subsection 868.5270

**Intended device:** Breathing circuits for use with SCT 3000 Heated Humidifier

**Predicate devices:** Marquest SCT 3000 - K903138  
Marquest (Intec) - Heated limb - K860941  
Intertech ( SIMS) - K881231

**Device description:** Various configurations of anesthesia, volume ventilator circuits  
and heated limbs for use with SCT 3000 Heated Humidifier.

**Indicated use:**

Heated wire circuits to be used with the SCT 3000 are indicated as breathing circuits for patients under going anesthesia or mechanical ventilation.

**Targeted population:**

Any patient utilizing the SCT 3000 heated humidifier. Adult, pediatric and neonates.

**Environment of use:** Hospital, anesthesia, ICU, respiratory therapy

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**Comparison to predicate devices:**

<b>Attribute</b>	<b>Marquest Heated Wire Circuits</b>	<b>Intertech / SIMS Heated Wire Circuits</b>
<b>Use</b>		
Indicated for anesthesia	Yes	Yes
Indicated for respiratory therapy	Yes	Yes
Population - adult, pediatric, neonate	Yes	Yes
Indicated for use with heated humidifiers	Yes	Yes
Indicated for use with only specific manufacturers heated humidifier	Yes	Yes
Indicated for single use	Yes	Yes
<b>Design</b>		
Various patient wye connectors	Yes	Yes
Breathing Tubes various lengths	Yes	Yes
Breathing Bags - various sizes	Yes	Yes
Single or dual heated wires	Yes	Yes
Anesthesia - rebreathing and non-rebreathing styles	Yes	Yes
Volume ventilator - different styles for ventilator manufacturers	Yes	Yes
Offered for ventilators without internal exhalation valves	Yes	Yes
Packaged with other devices - Filters, Face Mask, Gas sampling lines, etc.	Yes	Yes

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**Comparison to predicate devices: (continued)**

<b>Attribute</b>	<b>Marquest Heated Wire Circuits</b>	<b>Intertech / SIMS Heated Wire Circuits</b>
<b>Materials</b> Utilize same materials as standard breathing circuits exempt from PMN	Yes	Yes
<b>Performance Testing</b> Meets ASTM breathing systems standard	Yes	Yes

**Differences**

Any differences that do exist would not have a significant effect on the safety or effectiveness of the device.