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K962223

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

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

**Proprietary or Trade Name:** Accessories for Marquest SCT 3000 Heated Humidification System

**Common/Usual Name:** Accessories for heated humidifiers

**Classification Name:** 73 BTT - Respiratory Gas Humidifier (direct patient interface)  
Subsection 868.5450

**Intended device:** Humidifier chambers for use with SCT 3000 Heated Humidifier

**Predicate devices:** Marquest SCT 3000 - K903138  
HPD Medical - K864173  
Fisher & Paykel - K850647, K862923, K934140

**Device description:** The humidifier chambers offered for use with the SCT 3000.

- \* Adult - low flow humidifier chamber
- \* Adult - extended run humidifier chamber
- \* Pediatric - low compressible volume humidifier chamber
- \* Adult - hi flow humidifier chamber

**Indicated use:**

The humidifier chambers for the SCT 3000 are indicated for use with the SCT 3000 unit and to hold water required to humidify the air being delivered to patients.

**Targeted population:**

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

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**Environment of use:**

Hospital, anesthesia, ICU, respiratory therapy

**Comparison to predicate devices:**

| <b>Attribute</b>   | <b>Marquest humidifier chambers</b> | <b>HPD Medical / Fisher &amp; Paykel humidifier chambers</b> |
|--|-------------------------------------|--|
| <b>Use</b>   |                                     |  |
| Intended for use in anesthesia                                       | Yes                                 | Yes  |
| Intended for use in respiratory therapy                              | 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  |
| Indicated for use with adult and pediatric cases                     | Yes                                 | Yes  |
| <b>Design</b>  |                                     |  |
| Clear housing  | Yes                                 | Yes  |
| 15 /22 mm fittings for connection to circuit                         | Yes                                 | Yes  |
| Different sizes  | Yes                                 | Yes  |
| Water inlet ports  | Yes                                 | Yes  |
| Labeling delineating water levels on chamber                         | Yes                                 | Yes  |
| <b>Materials</b>   |                                     |  |
| Polystyrene / polycarbonate housing                                  | Yes                                 | Yes  |

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

| <b>Attribute</b> | <b>Marquest<br/>humidifier chambers</b> | <b>HPD Medical / Fisher &amp; Paykel<br/>humidifier chambers</b> |
|------------------|---|--|
|------------------|---|--|

**Materials (continued)**

|                               |     |     |
|-------------------------------|-----|-----|
| Aluminum base / heating plate | Yes | Yes |
|-------------------------------|-----|-----|

**Performance Testing**

|                 |     |     |
|-----------------|-----|-----|
| None applicable | Yes | Yes |
|-----------------|-----|-----|

**B. Differences**

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