

# F: 510(k) Summary of Safety & Effectiveness

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## Safety

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWG, Patient Warming System called the Bair Hugger® Total Temperature Management System®-Modification. The following summarizes safety issues related to the use of rolling stands and the measures to prevent these problems.

### 1. Summary of Safety:

#### A. Stability:

The Rolling Stand could be inadvertently tipped over.

Prevention: The Rolling Stand has 5 legs to provide additional stability and meets the stability requirements of UL 2601-1 and IEC 601-1.

#### B. Use of stand with unapproved devices or products:

Use of the rolling stand with any device or product other than those provided by Augustine Medical, Inc. could result in damage to the stand, the attached product, or in the stand tipping over.

Prevention: Instructions packaged with the Model 90022 Rolling Stand include the statement "The Rolling Stand is not intended to be used with any device or product other than those provided by Augustine Medical, Inc."

### 2. Summary of Effectiveness

The Model 90022 Rolling Stand effectively supports the Bair Hugger Model 505 Warming Unit and provides effective transportation of the unit when used under normal operating conditions.

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