

K970295

EXHIBIT H

**510(k) Summary
FLEXICAIR® ECLIPSE™**

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1. SUBMITTER NAMES:

**Submitter: Hill-Rom® Inc.
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2. DEVICE NAMES:

**Common or Usual or
Classification Name: Portable Powered Flotation Therapy Mattress
Proprietary Name: FLEXICAIR® ECLIPSE™ Plus and Ultra**

3. PREDICATE DEVICES

**FLEXICAIR® ECLIPSE™ K951001) manufactured by Hill-Rom
FIRST STEP (K930673) manufactured by KCI Therapeutic Services.**

4. SUBJECT DEVICE

A. Air Supply Unit

The blower, controller and valves are located in an air supply which hangs on the footboard of the bed or can sit on the floor for the standard FLEXICAIR® ECLIPSE™ and the FLEXICAIR® ECLIPSE™ PLUS. For the FLEXICAIR® ECLIPSE™ ULTRA the air supply unit can sit on a tray at the left hand foot of the Magnum/Magnum II bed or can sit on the floor.

To accommodate the higher patient weight ranges there is a separate microprocessor control board, which can be programmed by the caregiver for FLEXICAIR® ECLIPSE™ PLUS and FLEXICAIR® ECLIPSE™ ULTRA configurations.

B. Mattresses

The standard FLEXICAIR® ECLIPSE™ will go on many different bed frames. The overall height is 8" with twenty-one 6" cushions attached by Velcro to a 2" substrate. The cushions also snap to side panels for added stability. The mattress is secured to the hospital bed frame by the means of three straps. Ability to

B. Mattresses (continued)

transport the patient is provided by the low-airloss feature which controls deflation over a 45 minute period.

The FLEXICAIR® ECLIPSE™ PLUS is designed to go on the Hill-Rom Century, Centra and Advance 1000 bed frames. The overall height is 9.5" and there are eighteen cushions in three layers separated into 6 independent zones. The top layer is the low-airloss cushion set, zone 1, and the lumbar support, zone 2. The middle layer, which is the comfort cushion set, is made up of three zones: zone 3 is the seat section; zone 4 is the back section and zone 5 is the foot section. Zone 6 is on the bottom layer which is the substrate.

The FLEXICAIR® ECLIPSE™ ULTRA is designed to go on the Hill-Rom cushions in three layers separated into 6 independent zones. The top layer which is the low-airloss cushion and includes two low-airloss side cushions is zone 1. The lumbar support cushion, which is zone 2, is also on the top layer. The middle layer, which is the comfort cushion set, is made up of two zones: zone 3 is seat section and zone 4 is the back section. Zone 5 is the foot section and zone 6 is the bottom layer which is the substrate.

C. Valves

The FLEXICAIR® ECLIPSE™ utilizes proportional valves. The proportional valve is a stand alone valve that controls itself to a set pressure and will match the output pressure with the signal from the controller.

5. INDICATIONS FOR USE

The standard FLEXICAIR® ECLIPSE™, the FLEXICAIR® ECLIPSE™ PLUS and the FLEXICAIR® ECLIPSE™ ULTRA Mattress Replacements are intended to provide low-airloss therapy for different ranges of patient weights. The standard FLEXICAIR® ECLIPSE™, used on general Med-Surg or specialty beds covers all patient weights up to 300 lbs. The FLEXICAIR® ECLIPSE™ PLUS covers patient weights from 301 lbs to 450 lbs on Hill-Rom Century, Centra and Advance 1000 bed frames and on the Stryker MPS bed frame. The FLEXICAIR® ECLIPSE™ ULTRA covers patient weights from 451 to 800 lbs on the Hill-Rom Magnum/Magnum II bed frames.

Air-fluidized and low airloss beds have been used for comfort and therapy for individuals who could not move themselves. Low airloss therapy has been demonstrated to reduce the risk of pressure ulcers caused by loss of capillary circulation as well as be a valuable aid in the treatment of bed sores.

Low airloss therapy maintains patient's peripheral circulation by distributing the patient's weight over cushions filled with air. The even distribution of pressure on the skin limits capillary closure, thereby helping maintain tissue viability around bony prominence such as the sacrum and heels. The numerous cushions in the FLEXICAIR® ECLIPSE™ help to decrease shear forces against the skin by moving independently of one another while the fabric helps to decrease friction.

5. **INDICATIONS FOR USE (continued)**

A non-permeable cover, or coverlet, placed over the cushions prevents the transmission of perspiration and body fluids to the cushions.

6. **COMPARISON TO PREDICATES**

Differences in design between the subject device and the predicate are as follows, none of which have significant effect on safety and efficacy.

1. **Air Supply Unit**

The blower, controller and valves are located in an air supply unit in both the FLEXICAIR® ECLIPSE™ and the FIRST STEP®. The air supply unit hangs on the footboard of the bed or can sit on the floor as in the FIRST STEP® Air Therapy Surface. Unlike the FIRST STEP®, all configurations of the FLEXICAIR® ECLIPSE™ provide inflated cushions for a forty-five minute period following disruption to power without the use of batteries. This accomplished through the output manifold.

2. **Mattresses**

The First Step® Air Therapy Surface has 28 cushions configured as a mattress overlay. The standard FLEXICAIR® ECLIPSE™ has twenty-one 6" cushions on a 2" substrate. The FLEXICAIR® ECLIPSE™ PLUS will go on the Hill-Rom Century, Centra and Advance 1000 bed frames and the Stryker MPS bed frame. The PLUS has eighteen cushions configured in three layers with an overall height of 9.5". The FLEXICAIR® ECLIPSE™ ULTRA, which will go on Magnum and Magnum II bed frames, has fifteen cushions also configured in three layers with an overall height of 9.5". All three FLEXICAIR® ECLIPSE™ mattresses are secured to the hospital bed frame by the means of three straps. Ability to transport the patient is provided by the control of air discharge providing 45 minute time for deflation. On the FIRST STEP®, the patient is allowed to 'bottom' on the mattress during transportation.

3. **Valves**

The FLEXICAIR® ECLIPSE™ uses proportional valves which are stand alone valves that control to a set pressure and will match the output pressure with the signal from the controller.

SUMMARY

These enhancements to the FLEXICAIR® ECLIPSE™ and to the predicate are designed for use in the prevention and treatment of pressure ulcers in obese and morbidly obese patients. They are mattress replacement products designed to use with hospital or specialty bed frames already in the facility.

During normal operation, the unit is powered from the same source used by the Hill-Rom predicate device . The air supply unit consists of the same types of major components as the Hill-Rom predicate device but programmed for higher patient weight ranges and packaged to be placed on the floor under the bed, to sit on a tray at the foot of the bed or to hang on the footboard. The mattresses are similar to those used in the predicates.

Any differences between these mattress replacements and overlays, including design, materials and energy sources, and the predicates are insignificant.