GAYMAR

GAYMAR INDUSTRIES, INC.

APR 30 1997

K962788

# Premarket Notification [510(K)] Summary

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**Date Summary Prepared:** January 30, 1997

**Device Name:** CLINI-DYNE Rotational Therapy System

**Common Name:** Rotation/Low Air Loss System

**Classification Name:** Alternating Pressure Air Flotation Mattress per 21 CFR, Section 880.5550

**Predicate Device:** CLA 1400 System

**Intended use of Device:**

**The CLINI-DYNE rotational/low air loss system is a patient rotation, pressure relieving support system used for the treatment and prevention of decubitus ulcers, urinary tract blockage, to aid circulation and for complications associated with immobility.**

**Description:** **The CLINI-DYNE Rotational Therapy System consists of an electromechanical inflation pump control unit which is connected to a mattress with cells (air filled bladders) through hose assemblies connected to the inflation pump. The system affords programmed patient position changes by gently turning the patient from supine to left side or right side and back to supine position when staff is unable to do so or needs assistance.**

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**Substantial Equivalence:**

**The following tables, CLINI-DYNE substantial equivalence matrix and the safety testing comparison table, summarize the technological characteristics and the nonclinical performance data upon which the substantial equivalence submission was made to the Food and Drug Administration.**

# *CLINI-DYNE SUBSTANTIAL EQUIVALENCE MATRIX*

7/11/96

| | *CLA-1400* (Predicate) | *CLD-1000* |
|---|---|---|
| **PERFORMANCE** | | |
| Patient Support Surface | Overlay | Mattress |
| Air Source | Blower | Electro-mechanical reciprocating pump |
| Pressure control mechanism | Microprocessor controlled pressure relief valve | Microprocessor controlled pressure relief valve |
| Voltage | 120v 60Hz Nominal | 120v 60Hz Nominal |
| Ambient | 60-90°F | 60-90°F |
| Tissue interface pressure measurements | Pressure relief | Pressure relief |
| Rotation angle | 0-45° | 0-40° ** |
| **Safety** | | |
| Maximum allowable pressure controlled by | Mechanical relief valve (55-60 mmHg) | Mechanical relief valve (56 mmHg) |
| CPR Deflate mechanism | Quick-disconnect feature of hose from pump | Remove panel at mattress |
| | | |
| **Physical characteristics** | | |
| Construction (Patient support surface) | Air filled cells used as an overlay | Air filled cells contained in a foam crib used as a mattress |
| | | |
| **Function & Intended uses** | | |
| Type of therapy provided | Treatment of the diseases of immobility and treatment of pressure ulcers | Treatment of the diseases of immobility and treatment of pressure ulcers |
| (Primary) Target population | Acute care and alternate care settings | Acute care and alternate care settings |
| Life Expectancy (pump) | Reusable* | Reusable* |
| Life Expectancy (cell) | Resusable* | Reusable* |
| **Product Labeling** | Refer to TAB C - *LABELING* | Refer to TAB B - *LABELING* |
| | | |
| **Approvals** | UL 544 | UL 2601-1 (submitted) |

* Cleanable using suggested disinfectants and cleaning agents.

** Dependent on physical characteristics of the patient. (40° minimum when set at maximum angle setting for each patient.)

file clneqmtx.xls

# COMPARISON OF MAJOR CHARACTERISTICS

| Characteristic | CLA-1400 (PREDICATE) | CLD-1000 |
|---|---|---|
| **Alerts** | | |
| Audible Alerts | yes | yes |
| Alert Silence (minutes) | 30 | no |
| Head of Bed Elevation Alert | yes | no* |
| Out of Rotation Alert | yes | no* |
| Siderail UP/Down Alert | yes | no* |
| Visual Alerts | yes | yes |
| **Rotation** | | |
| Automatic Left Only | yes | yes |
| Automatic Left to Right | yes | yes |
| Automatic Right Only | yes | yes |
| Center Only (no rotation) | yes | yes |
| Manual Left Only | yes | yes |
| Manual Right Only | yes | yes |
| Var.Angle, Min.range (degrees) | 0-45 | 0-45 |
| Variable Rate | yes | yes |
| Rotation Cycle Times (minutes) | 90, 30, 10, 2 | 60, 45, 30, 15 |
| **Cushion** | | |
| Placed onto Hospital Bed | yes | no (mattress replacement) |
| CPR Deflate | yes | yes |
| Low Air Loss | yes | yes |
| Pressure Relieving | yes | yes |
| Support Surface Inflation Control | yes | yes |
| Disposable Covers | yes | no** |
| Disposable Support Surface | yes | no** |
| Footboard/Foot Support Cushion | yes | yes |
| **Air Control Pump** | | |
| 120 Volt AC | yes | yes |
| 60 Hz | yes | yes |
| Amperage | 1-5 | 1 |
| Control Panel Lock-out | yes | yes |
| Microprocessor Control | yes | yes |
| U.L. Listed | yes | yes |
| Weight (lbs.) | 25 | 19 |

* See Substantial Equivalence

**Reusable mattress

5/6/96

## VI. SAFETY SUMMARY

### Safety Testing Comparison Table

| | | CLA 1400 | CLD 1000 |
|---|---|---|---|
| **Biocompatibility** | | | |
| a) | primary skin irritation | pass | pass |
| b) | delayed contact sensitization | pass | pass |
| c) | cytotoxicity | pass | pass |
| **Tissue Interface Testing** | | pass | pass |
| **Flammability** | | pass | pass |
| **UL Approvals** | | UL 544 | UL 2601-1 (pending) |
| **Alerts** | | | |
| a) | hi/low pressure | yes | yes |
| b) | out of range | yes | yes |