**RID-Decube II**

K965207

**510(k) SUMMARY**

AUG 21 1997

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|---|---|---|
| 1. | Submitter's Name | Skin Care Management, Inc. |
| | Address | 202 East Maple Street<br>Jeffersonville, Indiana 47130 |
| | Telephone Number: | (800) 682-7163 |
| | Contact Person: | John Keesaer |
| | Date Prepared: | December 18, 1996 |
| 2. | Trade Name: | RID-Decube II |
| | Common Name | Alternating Pressure Air Flotation Mattress |
| | Classification Name: | Alternating Pressure Air Flotation Mattress<br>Class II CFR 21 880.5550 |
| 3. | Predicate Device | Air Flow 5000 Manufactured by Atlantis Medical |
| 4. | Description: | The RID-decube II is an alternating pressure air flotation mattress intended for medical purposes with multiple air cells that can be filled and emptied in an alternating pattern by associated control units to provide regular, frequent and automatic changes in the distribution of body pressure. |
| 5. | Indications for Use | The RID-decube II is intended to be used to prevent and treat decubitus ulcers. |
| 6. | Substantial Equivalence | The product is similar in function and intended use as labeled to the Air Flow 5000 Manufactured by Atlantis Medical. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Skin Care Management
Eric Flam, Ph.D
President
NTL Associates, Incorporated
29 Ainsworth Avenue
East Brunswick, New Jersey 08816

AUG 21 1997

Re: K965207
Trade Name: Rid-Decube II
Regulatory Class: II
Product Code: FNM
Dated: May 22, 1997
Received: May 23, 1997

Dear Dr. Flam:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: RID-Decube II Alternating Pressure Mattress System

Indications For Use:

The RID-Decube II Alternating Pressure Mattress System is intended for medical purposes to be used to prevent and treat decubitus ulcers.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K965207

Prescription Use____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)