



510 (k) Summary

NOV 18 1997

K972549

- I. Name of Device:** **Simpulse™**
- II. Classification Name:** Class II, Mattress, Air Flotation, Alternating Pressure; (per 21 CFR Section 880.5550)
- III. Substantial Equivalence:** Premium 510(k) No. K930673
- IV. Device Description:**

The **Simpulse™** is a powered, Pulsating Therapy Mattress that can be used as an Overlay or Mattress Replacement System and is designed for use in all care settings (home, acute and extended). The **Simpulse** provides pulsating air suspension therapy that combines the benefits of pressure relief with the advantages of pulsation therapy.

The **Simpulse™** is comprised of two major components: the **Air Supply Unit**, and the **Mattress Assembly**.

The **Mattress Assembly** is comprised of: the pulsating air surface, the air base, the underliner and the cover sheet. The pulsating air surface is the component that pulses. It consists of ten separate interlocking air cushions that are plumbed to provide pulsation (five cushions are plumbed to Channel A and five are plumbed to Channel B). By only inflating the 5 inch pulsating air surface, the **Simpulse™** can be used as a mattress overlay.

When the **Simpulse** is used as a **Mattress Replacement System**, the 3 inch air base is inflated and serves as a static pressure air base that keeps the patient suspended when the bed is articulated. It also serves as an air support and remains inflated in case of a power outage. The underliner serves as an envelope to provide structure to the mattress. It has tie points that snap together and hold the pulsating air surface in place in relation to the air base. It also has straps that secure the entire **Mattress Assembly** to the bed frame.

The cover sheet is a fitted sheet made of nylon with a urethane backing that fits over the **Mattress Assembly** and provides a protective barrier between the patient and the air bladders.

The **Air Supply Unit** is mountable on the footboard of a standard hospital bed or can be placed upright on the floor and is microprocessor controlled to achieve the two modes of operation (Pulsation and/or Static). All user input to the microprocessor control

is accomplished through the membrane panel switches which are located on the Air Supply Unit.

The Air Supply Unit utilizes two separate pump and valve assemblies to channel compressed air to the Mattress Assembly, creating two sections referred to as Channel A and Channel B. This provides a single target pressure for the entire mattress as well as the means for the mattress to pulsate. The hose set has a connection on one end that mates to an air connection on the side of the Air Supply Unit. This connection also serves as a CPR emergency air deflation system by simply disconnecting the hose from the Air Supply Unit. The other end connects to the air cushions (Channel A, Channel B and the Air Base).

The target pressure is set by pressing the "Soft/Firm" buttons located on the membrane control panel. These buttons have five LED's evenly spaced between them and the user can adjust the firmness of the mattress within the range of these five LED's. If the user pushes and holds one of the buttons, the LED location will not increment until the user releases the button and pushes it again. Once the user selects the pressure setting, the pressure feedback system will automatically maintain the pressure setting within a target pressure range of plus or minus 1" H₂O. If the actual pressure moves out of the target pressure range, the microprocessor controller will activate the corresponding pump to increase the pressure or open the corresponding valve to decrease the pressure until the pressure is within the target pressure range.

In the Static mode, all of the cushions in the air surface are inflated to an equal pressure and operate in a continuous pressure feedback mode as previously described. In the Pulsating On mode, the cushion closest to the footboard will decrease in pressure together with every other cushion along the mattresses length (Channel A), while the other set of cushions (Channel B) increase in pressure. Once the cushions of Channel A reach the lowest point and begin to increase in pressure, the cushions of Channel B start to decrease in pressure. When the Channel B cushions reach the minimum pressure and then begin to increase in pressure, the cushions of Channel A will once again begin to decrease in pressure. This completes a full cycle. By pressing the "Pulsation Cycle Time" button, the pulsation cycle time can be adjusted over a range of between 5, 10 or 20 minutes. An LED light will indicate which time period has been selected.

The "Auto Firm" control will fill Channels A & B and the Air Base to a maximum inflation level. During the time that Auto Firm is activated, The Pulsation On/Off buttons, Pulsation Cycle Time Button and the Soft/Firm buttons as well as their respective LED indicators will be disabled. The mattress will stay at the maximum inflation level until the Auto Firm Off button is pushed or twenty minutes elapse from the time the Auto Firm On button was first pushed. The Simpulse will then default to the same settings of operation as before the AutoFirm was activated.

INTENDED USE OF THE SIMPULSE™

The Simpulse mattress is for supporting bedridden patients in a manner that helps prevent and treat complications of immobility such as skin breakdown and decubitus ulcers. It employs a series of transverse inflatable cushions that can be sequentially inflated and deflated to provide pulsation pressures beneath the patient.

INDICATIONS

The Simpulse is indicated for patients who would benefit from:

A pressure relieving surface with the additional benefit of pulsation to assist in the prevention and treatment of the complications of immobility such as skin breakdown and decubitus ulcers.

CONTRAINDICATIONS

Patient conditions for which the application of Pressure Relieving Therapy in addition to Pulsation therapy are contraindicated include:

Unstable Spinal Cord Injuries.
Cervical or Skeletal Traction.

DIFFERENCES BETWEEN CURRENT AND PREDICATE DEVICES

The Simpulse is a modification of the predicate device Premium. Both products provide Pulsation therapy but the mechanical means in which they render the therapy is different.

The major differences between the Simpulse and the Premium predicate device are:

- The DynaPulse[®]/Premium is blower driven and the Simpulse uses two pumps.
- The DynaPulse[®]/Premium has a heater and the Simpulse does not.
- The DynaPulse[®]/Premium has an Alpha Numeric LED display and the Simpulse only uses LED lights
- The DynaPulse[®]/Premium has height and weight presets that the care giver can enter so the microprocessor can make pressure changes based on the height/weight data. With the Simpulse, the care giver must manually select the firmness of the mattress by pressing the "Soft/Firm" buttons.
- The DynaPulse[®]/Premium allows the care giver to change the intensity of the pulsation. The Simpulse pulses at only one pulsation intensity level.
- The DynaPulse[®]/Premium mattress has four sections (head, body, seat and feet) and each of the sections can have a different air pressure setting. The Simpulse has one mattress section and will maintain one pressure setting for the entire body.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. William H. Quirk
Director of Regulatory Affairs
Kinetic Concepts, Incorporated
P.O. Box 659508
San Antonio, Texas 78265

NOV 18 1997

Re: K972549
Trade Name: Simpulse
Regulatory Class: II
Product Code: FNM
Dated: August 18, 1997
Received: August 20, 1997

Dear Mr. Quirk:

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 requirement, 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

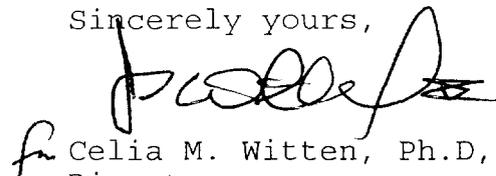
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



for Celia M. Witten, Ph.D, MD
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972549

Device Name: Simpulse

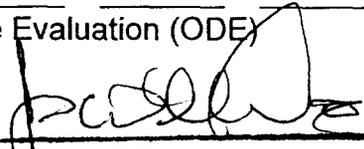
Indications for Use:

The Simpulse mattress is indicated for patients who would benefit from a pressure relieving surface with the additional benefit of pulsation to assist in the prevention and treatment of the complications of immobility such as skin breakdown and decubitus ulcers.

Note: The indications for use of the Simpulse are identical to the predicate device, Premium [510(k) No. K930673].

(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 **General Restorative Devices**

510(k) Number K972549

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)