K013436

DEC 21 2001

510(k) SUMMARY

NormaTec, Inc.'s NormaTec PCD

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Jonathan S. Kahan

Date Prepared: October 16, 2001

Name of Device and Name/Address of Sponsor

NormaTec PCD

Laura Jacobs, M.D., Ph.D.
60 W. Germantown Pike
E. Norriton, PA 19401

Common or Usual Name

Noninvasive pneumatic compression device

Classification Name

Compressible Limb Sleeve

Predicate Devices

Camp GCS 2000 (K935998), Wright Linear Pump (K830577), Talley Multicom 500 (K915637), Mego Afek Lymphapress (K810338), and Baxter Pulsatile Anti-Embolism System Pump (PAS II) (K911853).

Intended Use

The NormaTec PCD is intended to be used to apply pressure to the extremities. The NormaTec PCD is indicated for use in the treatment of:

Lymphedema and other edematous conditions, including

Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda)
Post-mastectomy lymphedema
Post-infection lymphedema
Post-traumatic lymphedema
Post-surgical lymphedema
Post-radiation-treatment lymphedema

Venous insufficiency

Venous stasis ulceration

and the prevention of:

Deep Vein Thrombosis

Technological Characteristics and Substantial Equivalence

The NormaTec PCD is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics. Both NormaTec's PCD and its predicates are intended to apply pressure to the extremities to treat edematous states like lymphedema, and to prevent deep vein thrombosis.

NormaTec's PCD has very similar components as its predicate devices and very similar principles of operation. Each device consists of an electrically generated source of compressed air, tubing to convey the pressurized air to the sleeve, control of pressure applied cyclically and simultaneous treatment of two limbs, if necessary. Like the predicates, pressure is pulsed to the affected limb for a specified period of time, followed by a rest period, according to the physician's prescription.

Performance Data

The NormaTec PCD underwent electromagnetic interference testing, burst testing, safety testing and quality assurance testing. In all instances, the NormaTec PCD functioned as intended and the results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2001

Normatec
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street
Washington, DC 20004-1109

Re: K013436
Trade Name: NormaTec PCD
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: II
Product Code: JOW
Dated: October 16, 2001
Received: October 16, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known): K013436

Device Name: NormaTec PCD

Indications for Use: The NormaTec PCD is intended to apply pressure to the extremities to treat:

Lymphedema and other edematous conditions, including

Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda)
Post-mastectomy lymphedema
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Post-traumatic lymphedema
Post-surgical lymphedema
Post-radiation-treatment lymphedema

Venous insufficiency

Venous stasis ulceration

and to prevent:

Deep Vein Thrombosis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013436

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)