K022340

510k Summary
July 2, 2002

FEB 1 9 2003

TravelAir Portable Compression System

In accordance with 21 CFR 807.92 this summary is submitted by:

I. Name of Submitter

Dynamic Air Incorporated
3485 BankHead Highway
Atlanta, GA 30331

Contact: Brent Knight
ERN: 232094

II Device Name and Classification

Proprietary Name: TravelAir Portable Compression System
Common or Usual Name: Compressible Limb Sleeve
Classification: Class II: IRP 890.5650

III Predicate Device

The TravelAir Portable Compression System is substantially equivalent to devices currently in commercial distribution by the following company:

Medical Compression Systems'
117 Ahuzah Street
Ra'ananna, IS 43373

Wizair (K002287)

Talley Medical Group
Progressive Medical Technology, Inc
815 Terminal Road
Lansing, MI 48906

DVT275 (K915638)

IV. Description of Device

The Dynamic Air, Inc. TravelAir Portable Compression System consists of a battery operated compression pump connected to an inflatable leg wrap. The compression pump is connected to the leg wrap by plastic tubing connected by CPC quick connectors at the pump and at the tubing /wrap junction.

The leg wrap consists of a Polyvinyl chloride (PVC) air bladder encapsulated inside a VelFoam material; the color of the outer covering material is white. The VelFoam material is adhered to the PVC air bladder. The wrap is provided clean, non-sterile packaged in pairs for use.

The compression pump consists of a medical grade micro pump which delivers preset pressures to the leg wraps. The micro pump is controlled by a microchip controller board which regulates pressure and compression time on a set cycle.

The compression pump inflates and deflates the leg wraps in a preset sequence intermittently compressing the soft tissue of the legs. This compression forces blood to move toward the heart and enhances venous return from the lower legs. After compression the wraps deflate and allow the veins and capillaries to refill. The cycle then repeats until the unit is deactivated.

V Intended Use and Contraindications

The TravelAir Portable Compression System is intended to assist in the relief of the following:

Fatigue in the lower limbs
Venous congestion in the lower legs
Edema in the lower legs
Edema in the lower legs post injury or trauma

Prevention of Deep Vein Thrombosis

Contraindications For Use of the TravelAir Portable Compression System

Acute pulmonary edema
Acute congestive heart failure
Acute diagnosis of DVT
Acute infection of the limb to be compressed
Open wounds of the limb to be compressed

VI Technical Characteristics

The TravelAir Portable Compression System is similar in to the predicate device in its operation characteristics. The material in the leg wrap is similar in make up to the predicate devices. The mode of operation and delivery of therapy is similar.

Bench testing performed by Dynamic Air has show that the leg wraps are substantially equivalent in performance to the predicate devices.

VII Performance Standards

There are no performance standards for this class of medical device (class II). Bench testing and side by side comparisons were done with predicate devices to assure equivalence in performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Dynamic Air, Inc.
c/o Mr. Brent Knight
Vice President Products
3495 Bankhead Highway, Suite A
Atlanta, GA 30331

Re: K022340
Trade Name: TravelAir Portable Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: November 9, 2002
Received: November 21, 2002

Dear Mr. Knight:

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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

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

Enclosure

Indications for Use Statement

510 (k) Number K022340

Device Name **TravelAir Portable Compression System**

Indications forUse

The TravelAir Portable Compression System is designed to provide intermittent compression of the lower legs to enhance venous return toward the heart. This venous enhancement is meant to relieve aches and fatigue in the legs brought on by long periods of immobility and reduce edema or swelling after sports injury or minor trauma.

Contraindications for this Device Would Include:

Acute congestive heart failure
Acute pulmonary edema
Existing Deep Vein Thrombosis
Acute infection of the leg to be compressed
Presence of skin ulceration on area to be compressed

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 Cardiovascular, Respitory,
And Neurological Devices
510(k) K022340

Prescription Use X **Over The Counter Use** ____
(per 21 CFR 801.109)