AUG 2 8 2003

K032325

510(k) Summary
Of Safety and Effectiveness

This submission covers the indication that compression stockings in the 15-20mmHg range and higher, such as the JOBST Travel Socks, help prevent deep vein thromboses (DVT). These products fall under the device classification of medical support stockings (21 CFR §880.5780). The Jobst Travel Socks are equivalent to the Jobst Anti-Em/GP stocking (K955138), which is indicated for use for the individuals subjected to long periods of immobility.

Both products are manufactured on circular knit machines. Both products are made of nylon and spandex yarns and provide compression at the ankle of approximately 15-20mmHg. However, the JOBST Travel Socks also have cotton yarns for added comfort. While both products are sized based on calf circumference, sizing information based on ankle circumference and shoe size will also be provided with the JOBST Travel Socks, for the convenience of the traveler.

Compression is provided for these products by elastic yarns that act circumferentially on the limb. The gradient compression present in these products helps reduce capillary leakage, prevent pooling of blood and improve blood flow. Consequently, they act prophylactically to help reduce the risk of developing deep vein thromboses (DVT) and superficial thromboembolisms.

The product being submitted is substantially equivalent to the predicate product in the materials used, mode of action, and indications for use and can be considered as safe and effective as the predicate product.

Date: August 27, 2003

Prepared by: Angelo R. Pereira
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5825 Carnegie Boulevard
Charlotte, NC 28209
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2003

Mr. Angelo Pereira
Manager, Regulatory Affairs
BEN-JOBST Incorporated
5825 Carnegie Boulevard
Charlotte, North Carolina 28209-4633

Re: K032325
Trade/Device Name: Jobst Travel Socks
Regulation Number: 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: July 25, 2003
Received: July 28, 2003

Dear Mr. Pereira:

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) 594-4618. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032325

510(k) Number

Device name: **Jobst Travel Socks**

Indications For Use: Over-the-Counter

Jobst Travel Socks are indicated for the following conditions:

Help prevent edema and leg discomfort and help prevent deep vein thrombosis for long distance travelers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR Over The Counter Use**_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032325