AUG 20 1999

K991570

510(k) Summary of Safety and Effectiveness

This submission covers JOBST Ready-To-Wear Compression Arm Sleeves, which fall under the device classification of medical support stockings (21 CFR §880.5780). They are equivalent to the preamendment Jobst-Custom garments, and the SIGVARIS 902/503 Arm Sleeves, which are used for the same indications.

While Jobst-Custom garments are cut and sewn from fabric made of spandex and nylon yarns, the SIGVARIS 902 and JOBST Ready-To-Wear Arm Sleeves are circular knit with spandex and nylon yarns.

The sizing of the Ready-To-Wear Arm Sleeves is based on circumferential measurements of the wrist, forearm and mid-upper arm and is limited to people whose arm dimensions fall within the specified ranges. The Jobst-Custom garments are sized based on measurements taken every inch and a half. They can be made to fit a wider range of limb dimensions and a wider range of compression as needed by the individual patient.

Compression is provided for all of these products by large elastic yarns that act circumferentially on the limb. The gradient compression present in these products helps to force fluid into the deep venous system and helps in the return of lymphatic fluid. Consequently, they can be used to manage the same indications, i.e. CVI, edema, lymphedema, phlebitis, post-thrombotic syndrome and vascular malformations. These products can also be used to manage hypertrophic scars and post liposuction for the arms. The contraindications for these products are also the same, i.e. significant arterial insufficiency, cutaneous infections, dermatitis in the acute phase, wet dermatosis and conditions in which venous and lymphatic return is not desired.

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

Date: May 4, 1999

Prepared by: Angelo R. Pereira
Beiersdorf-Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, NC 28209
Phone: (704) 551-7178

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1999

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

Re: K991570
Trade Name: Jobst Ready-To-Wear Arm Sleeves
Regulatory Class: II
Product Code: DWL
Dated: July 30, 1999
Received: August 02, 1999

Dear Mr. Pereira:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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: K991570

Device name: **Jobst Ready-To-Wear Arm Sleeve**

Indications For Use: Over-the-Counter

Jobst Ready-To-Use Arm Sleeve may be used under the direction of a healthcare professional to manage the flowing conditions:

Edema
Mild to moderate lymphedema
Phlebitis
Post-thrombotic syndrome
Vascular Malformations
Hypertrophic scars

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K991570