K974 10422

JAN 13 1998

510(k) Summary
of Safety and Effectiveness

This submission is being made for a sterile version of the sleeve used for the Jobst Athrombic Pump System 2500. This product is a Class II device and is classified as a compressible limb sleeve under 21 CFR 870.5800.

The sterile sleeve/Jobst Athrombic Pump System 2500 combination is substantially equivalent to the Kendall Healthcare Product's sterile sleeve/SCD compression system in its mode of operation and indications for use. Both products are used to help prevent deep vein thrombosis and pulmonary embolism in recumbent patients by increasing deep venous blood flow from the lower extremities. This is accomplished by intermittent compression of the muscles in the lower limbs. Both sleeves are made of PVC and are sterilized with ethylene oxide.

The Jobst Athrombic Pump System 2500 with the non-sterile sleeves has been on the market since 1994 and has proven to be safe and effective in that time. The sterile version is being offered for situations where sterile product is preferred.

Date: March 11, 1997

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 20856

JAN 13 1998

Mr. Angelo R. Pereira
Manager, Regulatory Affairs
Beiersdorf-Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, NC 28209-4633

Re: K970922
Jobst Athrombic Pump/Sleeve
Regulatory Class: II (Two)
Product Code: 74 JOW
Dated: March 28, 1997
Received: March 31, 1997

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 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 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K970922

Device Name: Sterile Sleeve for Jobst Athrombic Pump

Indications for Use:

Increase blood flow from lower extremities in recumbent patients to help prevent deep vein thrombosis (DVT) and pulmonary embolism (PE)

(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)

Optional Format 1-2-96)

D A Spyk

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970922