

K980456

MAY 5 1998

510(k) Summary Statement

The following is a summary of the premarket 510(k) notification to the Food and Drug Administration as to Beiersdorf - Jobst, Inc.'s intention to manufacture and market a gradient sequential athrombic pump system.

Trade Name: Jobst Athrombic Pump System 2600

Common/Usual Name: Athrombic Pump®

Classification Name: Class II - 74JOW Patient Maintenance Device, Sleeve, Compressible, Limb (21 CFR 870.5800)

Claimed Equivalent Device: Jobst Athrombic Pump System 2500
Manufactured by: Beiersdorf - Jobst, Inc.

Device Description:

The System 2600 is a three component system consisting of a control unit, inflatable multi-segment leg sleeves, and conduit tubing (4 port) with detachable connections. The control unit is an electro/mechanical device designed to apply a specific degree of pressure to the leg in a precise cycle beginning at the ankle (or lower calf) and continuing sequentially to the thigh. The unit utilizes a software based electronic control system, electro/mechanical compressor, and solenoid operated air inflation control valves. All electrical and mechanical components are contained in a molded plastic housing.

Pressure is generated in the control unit and is transferred to the patient by air inflation of the multi-segment leg sleeves. The segments are inflated sequentially to various pressure settings to create a decreasing gradient, distal to proximal, on the lower extremity.

The inflatable multi-segment leg sleeves are designed to be wrapped comfortably around the patient's leg. They consist of multiple air chambers which can be inflated independently. There are four sizes of sleeves offered for use with the system. Two sizes have all four air chambers positioned between the ankle and knee. The other two sizes position two chambers between the ankle and knee and two chambers above the knee on the thigh.

The Jobst System 2600 monitors the sleeve pressure repeatedly during sleeve segment inflation via a pressure transducer. Solenoid activated valves, controlled by the electronic control system, regulate the air pressure in the segments. Each segment's pressure is controlled by specific solenoid valves and is isolated from the other segments. Segment inflation and cycle timing are based on each segment achieving a preset (non-adjustable) pressure within a maximum allowable time limit. The pressures in each segment are repeatedly monitored and corrected throughout the cycle to ensure the preset pressures are maintained within each segment. After the four segments in the sleeve are

inflated in a sequential pressure gradient manner, the solenoid valves open and the air is exhausted. The creation of the gradient sequential condition is dependent on the sequential opening of the solenoid valves and the pressure, monitored by the pressure transducer, in each segment of the sleeve. The pressure setting is fixed and is not user selected.

Intended Use:

The System 2600 is intended to help prevent deep vein thrombosis and pulmonary embolism. By compressing the lower extremities of a recumbent patient in a gradient sequential repetitive squeezing and relaxing action, the system is providing a prophylactic modality classified in 21 CFR 870.5800 - Compressible Limb Sleeves.

Technological Characteristics Comparison

The following is a comparison between the Jobst System 2500 and the Jobst System 2600. Both devices supply gradient sequential compression used to help prevent deep vein thrombosis and pulmonary embolism and are equivalent in design and function. The System 2600 is the next generation of the System 2500 and is designed to perform the same inflation cycle and utilize the same inflatable multi-segment leg sleeves as the System 2500. The System 2600 is lighter and smaller than the System 2500 and is easier to service and maintain.

The design of both systems consist of the following three main components; a Control Unit (Pneumatic Compression Unit), inflatable multi-segment leg sleeves, and conduit tubing (4 port) with detachable connections.

The control units are both electro/mechanical devices designed to apply a selected degree of pressure to the leg in a precise cycle beginning at the ankle (or lower calf) and continuing sequentially to the thigh. The units utilize software based electronic control systems, electro/mechanical compressors, and solenoid operated air inflation control valves. Power is supplied via 115 VAC line current. All electrical and electro/mechanical components are contained in molded plastic housings.

The techniques and technology used to control pressure are the same in both control units. Both control units monitor the sleeve pressures repeatedly during sleeve segment inflation via a pressure transducer. Solenoid activated valves, controlled by the electronic control system, regulate the air pressure in the segments. Each segment's pressure is controlled by specific solenoid valves and is isolated from the other segments. Segment inflation and cycle timing are based on each segment achieving a preset (non-adjustable) pressure within a maximum allowable time limit. The pressures in each segment are constantly monitored and corrected throughout the cycle to ensure the preset pressures are maintained within each segment. After the four segments in a sleeve are inflated in a sequential pressure gradient manner, the solenoid valves open and the air is exhausted. The pressure setting is fixed and is not user selected.

Equivalency Based Performance Data:

The System 2600 and System 2500 were bench tested to determine equivalency. Both systems are programmed to execute the same inflation cycle. They use the same controlling parameters of time and target pressures. And, they also use the same sleeves during operation. Due to these similarities, inflation cycle parameters were measured and compared.

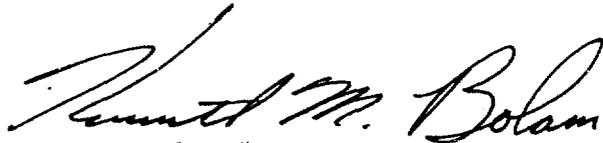
The results of the testing demonstrates that the inflation cycles executed by the System 2600 and System 2500 are equivalent. Both systems controlled the target pressures of 50 mmHg (segment 1), 45 mmHg (segment 2), 40 mmHg (Segment 3), and 30 mmHg (segment 4) within the same tolerance. The rise times (time required to reach target pressures) were under three seconds for both systems. Inflation times (total time a sleeve is inflated in a cycle) was less than 30 seconds for both systems. Total cycle time was approximately 60 seconds for both systems.

Equivalency Conclusions:

The Jobst Athrombic Pump System 2600 (calibrated gradient sequential unit with pneumatic sleeves) is substantially equivalent to the Jobst Athrombic Pump System 2500 (calibrated gradient sequential unit with pneumatic sleeves). Both devices supply gradient sequential compression to help prevent deep vein thrombosis and pulmonary embolism. The inflation / deflation cycle pressures and timing parameters are the same and they utilize the same four (4) port conduit tubing and inflatable multi-segment limb sleeves.

2/2/98

Date: 2/2/98



Prepared By: Kenneth M. Bolam
Director, Medical Equipment Development
Beiersdorf - Jobst, Inc.



MAY 5 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth M. Bolam
Director of Medical Equipment Development
Beiersdorf - Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, NC 28209-4633

Re: K980456
Jobst Athrombic Pump System 2600
Regulatory Class: II (Two)
Product Code: 74 JOW
Dated: February 3, 1998
Received: February 5, 1998

Dear Mr. Bolam:

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 requirements, 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.

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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, 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): K 980456

Device Name: Jobst Athrombic Pump System 2600

Indications For Use:

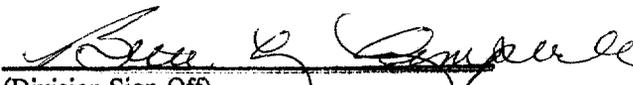
Increase blood flow from lower extremities in recumbent patients to help prevent deep vein thrombosis (DVT) and pulmonary embolism (PE).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 980456