K040084

APR - 7 2004

ADVANCED CIRCULATORY SYSTEMS, INC.

7615 Golden Triangle Drive (Suite A)
Eden Prairie, MN 55344
(952) 947-9590 (telephone)
(952) 942-8336 (facsimile)

510(k) Summary of Safety and Effectiveness

Company Name: Advanced Circulatory Systems, Inc.
7615 Golden Triangle Drive (Suite A)
Eden Prairie, MN 55344

Contact: Robert Cohen, Chief Executive Officer
Phone: 952 947-9615
Fax: 952 942-8336

Summary Date: April 5, 2004

Trade Name: Lifestyle Circulatory Enhancer (CE)

Common Name: Circulatory Enhancer

Classification Name: The predicate devices were found substantially equivalent to:
21 CFR 868.5690 Incentive Spirometer, Product Code: BWF
21 CFR 870.5800 Compressible Limb Sleeve, Product Code: JOW
21 CFR 880.5780 Medical Support Stocking, Product Code: DWL

Predicate Devices:

510(k)	Manufacturer	Product Code	Class	Trade Name
K022906	Advanced Circulatory Systems, Inc.	BWF, JOW	II	ResQPOD™ Circulatory Enhancer
K033401	Advanced Circulatory Systems, Inc.	BWF, JOW	II	Modification of the ResQPOD™ Circulatory Enhancer
K032325, K951234	Jobst A Beiersdorf Co.	DWL	II	Medical Support Stockings and other commercial names

1.0 Description of Device

The Lifestyle Circulatory Enhancer (CE) device is a non-sterile, single user device that is used within the external airway channel. Inspiration through the Lifestyle CE device provides temporary circulatory enhancement. Temporary circulation enhancement increases

blood pressure, which has a positive effect on the symptoms of orthostatic hypotension. The technology providing temporary circulatory enhancement is the same as in the predicate ResQPOD CE devices.

2.0 Intended Use

The Lifestyle CE device indication for use is:

> The Lifestyle Circulatory Enhancer (CE) is indicated for the temporary increase in blood circulation as prescribed by a physician or licensed practitioner. The Lifestyle CE may benefit people who suffer from states of poor circulation and low blood flow, including those individuals who suffer from orthostatic hypotension symptoms, such as lightheadedness, when moving from a sitting or reclining position to a standing position.

3.0 Technology

The technology of the Lifestyle CE device for the temporary increase in circulation is the same as the technology of the predicate ResQPOD CE devices; reference 510(k) K022906 and K033401.

4.0 Conclusions

The safety and effectiveness of use of the Lifestyle CE device was demonstrated by bench qualification, animal study and a review of investigator sponsored clinical studies. The intended use and technology of the Lifestyle CE device are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Advanced Circulatory Systems, Inc
c/o Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K040084
Lifestyle Circulatory Enhancer
Regulation Number: 21 CFR 868.5690, 870.5800, and 880.5780
Regulation Name: Incentive Spirometer, Compressible Limb Sleeve, and Medical Support Stocking
Regulatory Class: Class II (two)
Product Code: BWF, JOW, and DWL
Dated: January 12, 2004
Received: January 15, 2004

Dear Mr. Syring:

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) 594-4648. 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

510(k) Number (if known): K040084

Device Name: Lifestyle Circulatory Enhancer

Indications for Use:

The Lifestyle Circulatory Enhancer (CE) is indicated for the temporary increase in blood circulation as prescribed by a physician or licensed practitioner. The Lifestyle CE may benefit people who suffer from states of poor circulation and low blood flow, including those individuals who suffer from orthostatic hypotension symptoms, such as lightheadedness, when moving from a sitting or reclining position to a standing position.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Anne

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040084