JUN 11 2003

K022906

510(k) Summary

1.	Submitter:	**Advanced Circulatory Systems, Inc.** 7615 Golden Triangle Drive Suite A Eden Prairie, MN 55344 Tel: 952.947.9590 Fax: 952.942.8336
2.	Contact:	Meg Stapleton Advanced Circulatory Systems, Inc.
3.	Date prepared:	June 9, 2003
4.	Device trade name:	ResQPOD™ Circulatory Enhancer
5.	Common name:	Circulatory Enhancer
6.	Predicate device(s):	Compressible Limb Sleeve (JOW) Class 2 Spirometer, Therapeutic (Incentive) (BWF) Class 2
7.	Description:	The ResQPOD Circulatory Enhancer is a patient powered pump that uses a person's own negative intrathoracic pressures to create a vacuum in the chest cavity. The vacuum allows the heart to preload with more blood, thereby increasing blood circulation.
8.	Intended use:	The ResQPOD Circulatory Enhancer is indicated for use in people with poor circulation. The ResQPOD Circulatory Enhancer is indicated for home and hospital use for the temporary increase in blood circulation as prescribed by a physician or licensed practitioner.
9	Contraindications	The ResQPOD Circulatory Enhancer is contraindicated in persons with: 1. chest pain; 2. shortness of breath; 3. dilated cardiomyopathy and/or congestive heart failure; 4. pulmonary hypertension and/or aortic stenosis; and, 5. flail chest.
10.	Warnings	Safety and effectiveness in users suffering from arterial stenosis or asthma has not been established. Prescribing physicians or licensed practitioners should be aware of these conditions before prescribing use.

11. Precautions	The safety and effectiveness in pregnant women and children under the age of 18, and patients with hypovolemia, has not been established. Special care should be exercised for the safe and effective use of this device by such persons.
12. Technology comparison to predicate device(s):	The ResQPOD Circulatory Enhancer is similar in technological design to an Incentive Spirometer (BWF Class 2). The Indication of increased circulation is the same as the PPCID- Pneumatic Peripheral Circulation Improvement (K000655).
13. Non-clinical test summary:	Substantial equivalence to predicate devices was provided, in part, by non-clinical tests that demonstrate substantially equivalent product technology. Animal studies demonstrated an increase in circulation with the use of the ResQPOD Circulatory Enhancer device.
14. Conclusion:	The ResQPOD Circulatory Enhancer is substantially equivalent to the legally marketed 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

JUN 11 2003

Advance Circulatory systems, Inc.
Formerly CPRx
c/o Ms. Meg Stapleton
7615 Golden Triangle Drive, Suite A
Eden Prairies, MN 55344

Re: K022906
Trade Name: ResQPOD™ Circulatory Enhancer
Regulation Number: 21 CFR 868.5690 and 870.5800
Regulation Name: Incentive spirometer and Compressible limb sleeve.
Regulatory Class: Class II (two)
Product Code: BWF and JOW
Dated: March 12, 2003
Received: March 13, 2003

Dear Ms. Stapleton:

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.

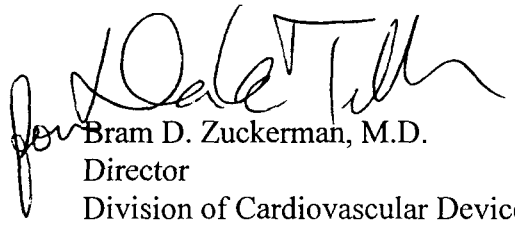
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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

Indication for Use Form

510(k) Number (if known): K022906

Device Name: ResQPOD™ Circulatory Enhancer

Indications For Use:

The ResQPOD™ Circulatory Enhancer is indicated for home and hospital use, for the temporary increase in blood circulation as prescribed by a physician or licensed practitioner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only (Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022906