K033401

NOV 2 0 2003

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: October 23, 2003

Trade Name: ResQPOD™ Circulatory Enhancer

Common Name: Circulatory Enhancer

Classification Name: The unmodified, predicate ResQPOD CE was found substantially equivalent to:
21 CFR 868.5690 Incentive Spirometer
21 CFR 870.5800 Compressible Limb Sleeve

Predicate Device:

510(k)	Manufacturer	Product Code	Class	Trade Name
K022906	Advanced Circulatory Systems, Inc.	BWF, JOW	II	ResQPOD™ Circulatory Enhancer

1.0 Description of Device

The modified ResQPOD Circulatory Enhancer (CE) device is mechanically and functionally equivalent to the unmodified, predicate ResQPOD CE reviewed and cleared for market in 510(k) K022906. This 510(k) submission was provided to review the following feature additions:

a) The addition of timing assist lights as a convenience to encourage proper inspiration rate through the ResQPOD CE;

b) Modified labeling to support use of the ResQPOD CE on alternative adjunctive airway devices, such as a mouthpiece, facemask with an ISO standard 22 mm connector, and endotracheal tube;

c) Provision for an ISO standard 15 mm to 22 mm adapter connector between the ResQPOD CE and the mouthpiece or facemask; and

d) Modified labeling to support use of the ResQPOD CE in clinic and emergency care locations with patients who, in the judgment of a physician or licensed professional, may need circulatory enhancement as provided by the ResQPOD CE.

2.0 Intended Use

The modified ResQPOD CE indication for use is:

> The ResQPOD Circulatory Enhancer is indicated for home, hospital, clinic and emergency care use, for the temporary increase in blood circulation as directed by a physician or licensed practitioner.

3.0 Technological

The technology of the modified ResQPOD CE device for temporary increase in circulation is the same as the technology of the ResQPOD CE device, reference 510(k) K022906.

The modified ResQPOD CE device is applied to adjunctive airway devices such as a mouthpiece, facemask or endotracheal tube. The skin contact material components of the modified ResQPOD CE are the same as those reviewed and cleared to market with the ResQPOD CE, 510(k) K022906 and are commercially available devices for respiratory use.

4.0 Conclusions

The safety and effectiveness of use of the modified ResQPOD CE device was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the modified ResQPOD CE device is substantially equivalent to the predicate, unmodified device. 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

NOV 2 0 2003

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

Re: K033401
Modified ResQPOD™ Circulatory Enhancer
Regulation Number: 21 CFR 868.5690 and 21 CFR 870.5800
Regulation Name: Incentive Spirometer and Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: BWF and JOW
Dated: October 23, 2003
Received: October 29, 2003

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033401

Device Name: ResQPOD Circulatory Enhancer, Modified

Indications For Use:

The ResQPOD Circulatory Enhancer is indicated for home, hospital, clinic and emergency care use, for the temporary increase in blood circulation as directed 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033401

(Optional Format 3-10-98)