SUBSTANTIAL EQUIVALENCE SUMMARY

This summary follows the format of the FDA 510(k) Substantial Equivalence Decision Making Process document.

EQUIVALENT (PREDICATE) DEVICE: **K945213** **(Teen 100) KB1-C Ambulatory Metabolic Measurement Systems**

Manufactured by:

AeroSport, Inc.
3518 West Liberty
Ann Arbor, MI 48103
Telephone: 313-668-3333
Fax: 313-741-0884

A. Does the KB1-C Ambulatory Metabolic Measurement Systems have the same indications statements?

Yes, both products are systems which telemetrically measure metabolic functions, as is the Cosmed K-4.

B. Does the KB1-C Ambulatory Metabolic Measurement Systems have the same technological characteristics, e.g., design, materials, etc.?

The two systems have substantially the same characteristics as demonstrated in the comparison chart located in this attachment. There is a difference in the type of flowmeter used in both devices. The Cosmed K4 employs a Bi-directional Turbine and the AeroSport KB1-C employs a Orifice pneumotachometer. Both of which measure flowrate.

The only other difference being the radio transmission; the Cosmed K4 uses a FM 433.920 MHz which is approved in Europe. However, the product is manufactured for many countries in the world and the carrier frequency for the output power can be decided by the customer in order to meet country regulations.

C. Could the new characteristics affect safety and effectiveness?

No, metabolic measurements are still accurately measured with both products. The software validation included in Attachment #6, demonstrates accuracy..

D. Do the new characteristics raise new types of safety or effectiveness questions?

No.

E. Do acceptable scientific methods exist for assessing effects of the new characteristics?

Not applicable.

F. Are performance data available to assess the effects of new characteristics?

A summary of the performance of accuracy testing is contained in Attachment #8.

G. Do performance data demonstrate equivalence?

Performance has been verified via Quality Control testing as explained in Attachment #8.

CONCLUSION:

The Cosmed K4 Portable Metabolic Measuring System and the AeroSport Teen 100 / KB1-C Ambulatory Metabolic Measurement System are substantially equivalent as demonstrated by information and literature contained in this pre-market notification document.

COMPARISON CHART:

The following table displays the similarities and differences of the new device to the marketed device to which equivalency is claimed.

COMPARISON FEATURE	COSMED K4	AEROSPORT KBC-1
INTENDED USE	Metabolic Measurements	Metabolic Measurements
MODE OF OPERATION	The subject wears equipment by a harness and breathes into a face mask held on by an anatomic cap. The respiratory flow, expiratory flow, gas concentrations (02 and C02) and heart rate are measured and transmitted to the Receiver Unit. Data collected are stored for later analysis on a personal computer for which software is supplies and run in **Windows Application.**	The subject wears the equipment by a harness and breathes into a facemask held by an anatomic cap. The respiratory flow, the expiratory gas concentrations (02 and C02) and the Heart Rage are measured and transmitted to the Receiver Unit. Data collected are stored for later analysis on a personal computer for which software is supplies and run in Windows Application.
MAJOR SEPARATE SYSTEM COMPONENTS	Portable Unit Receiver Unit Flowmeter (fixed to the facemask Heart Rate Monitor Belt	Portable Unit Receiver Unit Flowmeter (fixed to the facemask Heart Rate Monitor Belt
METABOLIC MEASUREMENTS	V02 (Oxygen Uptake) VC02 (C02 Production) VE (Ventilation) HR (Heart Rate)	V02 (Oxygen Uptake) VC02 (C02 Production) VE (Ventilation) HR (Heart Rate)
FLOWMETER TYPE	bi-directional Turbine	Orifice pneumotachometer
02 ANALYZER	Galvanic Fuel Cel	Galvanic Fuel Cel
C02 ANALYZER	Non-Dispersive Infrared	Non Dispersive Infrared
HEART RATE MONITOR	POLAR (Finland) Belt	Unknown
RADIO TRANSMISSION	FM433.920 MHz, Approved in Europe*	FM 902-928MHz
SOFTWARE	Internal Software in the Receiver Unit and Windows PC Software for data elaboration	Internal Software in the Portable Unit, Windows PC software for data elaboration.
PORTABLE UNIT: SIZE AND WEIGHT	170 x 48 x 90 mm 400 grams (+400 gm Battery Pack)	230 x 120 x 75 mm 1 Kg (weight of the battery pack unknown)
RECEIVER UNIT: SIZE AND WEIGHT	237 x 127 x 46 mm 1.2 kg	Not known
BIOCOMPATABILITY	The only part in contact with the patient is the face mask and the POLAR Heart Rate Belt. The mask is the same as the AeroSport KB1-C, and the POLAR belt is already sold in the US Market.	The only part in contact with the patient is the face mask and the heart rate belt. The mask is the same as used in the Cosmed K-4.

* The Cosmed K4 is manufactured for sale in many different countries, the carrier frequency for the output power can be decided by the customer in order to meet Country regulations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1997

Cosmed s.r.l.
c/o Ms. Anne Marie Cesario
Schiff & Company
1129 Bloomfield Avenue
West Caldwell, New Jersey 07006

Re: K963373
K4 Portable Metabolic Measurement System
Regulatory Class: II (two)
Product Code: 73 BZC
Dated: June 10, 1997
Received: June 12, 1997

Dear Ms. Cesario:

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.

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): K963373

Device Name: Cosmed K4 - Portable Metabolic Measurement System

Indications for Use:

The Cosmed K4 is a metabolic measurement system that allows telemetry monitoring of cardiorespiratory function during physical activities as well as in sports medicine and rehabilitation. The K4 measures, in real conditions, the ventilation, the O_2 consumption the CO_2 production and the heart rate of the person being monitored.

(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, Respiratory, and Neurological Devices
510(k) Number

Prescription Use ✓ **or** **Over-The-Counter Use** ______
(Per 21 CFR 801.109)

(Optional Format 1-2-96)