K993641

DEC 14 2000

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

AJW Technology Consultants, Inc.
962 Allegro Ln.
Apollo Beach, FL 33572

Phone: 813-287-2382
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Contact Person: Art Ward

Date of Summary: September 1, 1999

Trade Name: CORTEX METALYZER

Classification Name: Predictive Pulmonary Function Value Calculator
21 CFR Section 868.1890

Predicate Device: K980094 Oxycon Alpha Jaeger

Device Description/ Comparison:

The CORTEX METALYZER metabolic test system is a stationary device, which can monitor parameters during laboratory testing or simulated conditions. The device is comparable to the Jaeger Oxycon Alpha system.

The device is software driven. Adequate software testing with respect to the new IEC 601-1-4 has been conducted on the device. The device is electrically operated.

Intended Use:

The METALYZER is a pulmonary function stationary test system which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The METALYZER system provides predictive pulmonary function values are calculated based upon the data obtained during testing.

510(K) Summary
Differences and Similarities

As reviewed in Section 10 the Metalyzer pulmonary system is fundamentally similar to the predicate device. This summary reviews the:

Intended Use
Applications
Usage Location
Technological characteristics

Intended Use:

Both the Metalyzer and predicate device have the same intended use.

Applications:

Both products are used in applications such as stress testing, rehabilitation, sports research and medicine and occupational medicine.

Usage Location:

The Metalyzer and predicate device are designed for use within a laboratory or facility setting.

Technological Characteristics:

These products have very similar technology in their components.

Similarities:

Volume Transducer - Both use digital rotameter.
Carbon Dioxide Sensor – Non-dispersive infrared in both systems.
Heart Rate Sensor – Polar Belt used in both units.
Data Collection – A choice of mask or mouthpiece for collecting data offered in both.
Predictive Value Calculations – Both systems measure the same values and then calculate values for pulmonary function.

Differences:

Oxygen Sensor – The Metalyzer uses a Galvanic Fuel Cell while the predicate device a Paramagnetic Cell. Both types are considered standard technology for oxygen measurement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2000

Mr. Arthur J. Ward
Cortex Biophysik GmbH
c/o AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K993641
Metalyzer, Model 2: Metalyzer, Model 3
Regulatory Class: II (two)
Product Code: 73 BTY
Dated: September 13, 2000
Received: September 15, 2000

Dear Mr. Ward:

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993641

Device Name: CORTEX METALYZER MetabolicTest System

Indications For Use:

The CORTEX METALYZER pulmonary function stationary test system is a device which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The METALYZER system provides predictive pulmonary function values using the monitored and derived parameters. This device is for use in a laboratory or facility setting and may be used with adults and children over the age of 14 years.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K993641

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