K980908

SEP 11 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Lactate Pro™ System

I. General Information

Common Name of the Device:	Test for Lactate in whole blood Blood Lactate test meter
Trade Name of the Device:	Lactate Pro™ Test Strip Lactate Pro™ Blood Lactate Test Meter
Classification Information:	Lactate test system, 21 CFR 862.1450, Class I, KHP (Lactate Oxidase, Lactic Acid) Colorimeter photometer for clinical use, 21 CFR 862.2300, Class I
Submitter's Name/Address	KDK CORPORATION, Administration Division Kazuo Iketaki Deputy General Manager 57 NISHIAKETA-CHO, HIGASHI-KUJO, MINAMI-KU KYOTO 601-8045 JAPAN

II. Indications for Use

The Lactate Pro™ System is intended for the determination of Lactate in whole blood. The system is designed for the determination of blood Lactate by individuals with biochemical indicator of Lactic Acidosis. And evaluate physical performance or to establish a proper intensity of exercise for athletes. The system can be used in the home and in the clinical setting.

III. Device Description

The Lactate Pro™ System consists of Lactate Pro™ Blood Lactate Test Meter, Lactate Pro™ Test Strip.

IV. Substantial Equivalence

Lactate Pro™ System is used for the determination of blood Lactate by individuals with biochemical indicator of Lactic Acidosis. And as Lactate concentration increases in blood during exercises due to the lack of oxygen, Lactate can be measured to evaluate physical performance or to establish a proper intensity of exercises for athletes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 11 1998

Kazuo Iketaki
Deputy General Manager
KDK Corporation
57 Nishi Aketa-Cho
Higashi-Kujo, Minami-Ku
Kyoto 601, Japan

Re: K980908
Lactate Pro™ System
Regulatory Class: I
Product Code: KHP
Dated: August 21, 1998
Received: August 24, 1998

Dear Mr. Iketaki:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): unknown

Device Name: Lactate Pro™ Test Strips, Lactate Pro™ Blood Lactate Test Meter

Indications For Use:

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(Predicate Devices)

Boehringer Mannheim	ACCUSPORT	No. K951331
YSI, INC.	YSI MODEL 2300 STAT PLUS	No. K913806

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980905

(Optional Format 1-2-96)