

JUN 29 1998

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K982071.

Summary Prepared on:

Submitted by:

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Contact:

Paul VanDerWerf, Ph.D., Vice President Regulatory Affairs and Quality Assurance

Establishment Registration Number: 2245578

Identification of the Device:

| | |
|-------------------------|--|
| Device Name: | Lactic Acid |
| Proprietary/Trade Name: | i-STAT® Lactate test |
| Common Name: | Lactic Acid, Lactate |
| Classification Name: | Lactic acid test system. |
| Device Classification: | I |
| Regulation Number: | 21 CFR § 862.1450 |
| Panel: | Clinical Chemistry and Clinical Toxicology |
| Product Code: | KHP |

Identification of the Predicate Device:

Device Name: Stat Profile® Plus Ultra/Lactic acid test.

Intended use of the Device:

The Lactate test, as part of the i-STAT System, is intended for the *in vitro* measurement of the concentration of (lactate) lactic acid in fresh, arterial, venous or capillary whole blood. Blood samples may be untreated or treated with lithium heparin.

Description of the Device:

® i-STAT is a registered trademark of i-STAT Corporation, Princeton, NJ.
® Stat Profile is a registered trademark of Nova Biomedical, Waltham, MA.

The i-STAT lactate test is contained in a single use cartridge. In use, two to three drops of blood are placed in the cartridge as described below. The cartridge is inserted into the thermally controlled i-STAT Model 200 Portable Clinical Analyzer and all analytical steps are performed automatically. Patient and user information may be entered into the analyzer via a keypad during the automated analysis cycle.

The i-STAT System is an *in vitro* analytical system comprising a network of one or more portable clinical analyzers designed to be used at the point of patient care. The analyzers employ single-use test cartridges containing biosensor chips to perform diagnostic tests on whole blood. The system further comprises an infrared communications link from the analyzers to auxiliary information management devices such as printers, personal computers, laboratory information systems and hospital information systems.

The i-STAT analyzers, as part of the i-STAT System, are intended for use by health-care professionals for the *in vitro* analysis of arterial, venous or capillary whole blood at the point of patient care.

Tests with the i-STAT System are carried out in test cartridge. It houses the sensor array, aqueous calibrator, fluid channels, and a waste reservoir). Electrochemical sensors on biosensor chips are housed in cartridges in a variety of sensor test configurations appropriate to clinical needs.

Test panels are identified by name and color code on the cartridge label. In addition, test panel configurations are encoded into the cartridge in a mechanical feature in the cartridge housing. An array of electrical pins in the analyzer recognizes the mechanical feature and automatically identifies the cartridge test panel type.

In use, whole blood is introduced into the sample well of the cartridge at the sample port. After closure, the cartridge is inserted into the cartridge door of the analyzer. Insertion of the cartridge initiates a precisely controlled and monitored sequence of steps performed by the instrument without user intervention. These steps are:

- Electrical contact is made between the analyzer electronic input circuits and the cartridge. The analyzer identifies the type of cartridge being used and the tests contained in the cartridge.
- Calibrator is positioned over the sensors. Each lactate test is calibrated with calibrator fluid that contains a pre-determined amount of lactic acid.
- Calibration measurements are made as the sensors generate signals mathematically related to analytic concentrations. In the i-STAT lactate test the concentration of lactate is directly related to the appearance of hydrogen peroxide (measured by amperometrically) generated by lactic acid oxidase acting on lactic acid in the calibrator fluid or in the blood sample.
- Blood sample washes out the calibrator with the aid of an air bubble between the two.
- Blood sample is positioned over the sensors.
- Calculations of sample concentrations are performed and displayed.

The displayed results are also stored in the analyzer memory and can be transmitted by infrared communication link to commercially available computers or printers.

The lactate test cartridge is assembled from plastic components that provide the conduits for fluid handling and house the sensor chips. In the cartridge containing the test for lactate, the sensors comprise a patterned metallic layer, supported on a silicon/silicon dioxide substrate, coated with a thin membrane containing lactic acid oxidase.

Comparison of the Technological Features to the Predicate Device:

The following technological differences between the i-STAT lactate and the Nova test are noteworthy.

1. The Nova lactate has to be calibrated daily with a two-point calibration. The i-STAT lactate is automatically calibrated during each sample analysis cycle.
2. The Nova analyzer is a much larger multi-channel analyzer while the i-STAT system is a handheld device.
3. The Nova lactate sensor is a multiple-use analytical system and is therefore prone to contamination and carry-over while the i-STAT sensor is single use and free of such interferences.

Summary of Non-Clinical Test Performance in Support of Substantial Equivalence:

Studies using calibration verification solutions at five concentrations of lactic acid, has established that the i-STAT Lactate test is linear over the claimed reportable range of 0.3 to 20 mmol/L. The reportable range of the Nova Stat Profile Plus Ultra lactate test is also 0.3 to 20 mmol/L.

Imprecision of the i-STAT Lactate test was established over 20 days using duplicate aqueous controls. In the normal range the average (N=120) was 0.81 ± 0.03 mmol/L [3.3% c.v.]. In the abnormal range (N=120) was 6.35 ± 0.08 mmol/L [1.2% c.v.]. Within run precision (using control materials) for the Stat Profile Plus Ultra (N = 18-25) is reported to be 0.8 ± 0.05 mmol/L (6.1% c.v) in the normal range and 7.6 ± 0.19 mmol/L (c.v 2.5%) in the abnormal range.

Summary of Clinical Test Performance in Support of Substantial Equivalence:

Studies compared the i-STAT Lactate test (y) was to the predicate device (x) using blood (site 1) and to a standard laboratory instrument (x) using plasma (site 2). The methods were compared using Deming regression analysis. The results summarized in the table below indicate that the i-STAT test performance is similar to the predicate device.

| Statistic | Definition | Blood | Plasma |
|------------------|--|-------------|------------|
| | | Pred Device | Lab Device |
| N pairs | The number of patient samples | 46 | 47 |
| Mean | The average of the comparative method | 5.92 | 3.25 |
| Sx | The standard deviation of comparative method results | 3.485 | 2.091 |
| Syx | Standard error of the estimate of the regression of y on x | 0.154 | 0.146 |
| Slope | Deming linear regression slope | 0.993 | 1.118 |
| Intercept | Deming linear regression intercept | 0.036 | -0.052 |
| Range | Range of comparative method results | 0.9-13.2 | 0.81-13.2 |
| r | Correlation coefficient | 0.998 | 0.998 |
| Sxx | Pooled imprecision of x duplicates | 0.125 | 0.027 |
| Syy | Pooled imprecision of y duplicates | 0.106 | 0.054 |

Conclusions:

Based on the non-clinical data, the new i-STAT lactate test is usable over the range of 0.3 to 20 mmol/L. Studies using controls indicate adequate precision at normal and medical decision levels. Clinical data indicates acceptable correlation to plasma and whole blood instruments. Based on data from CAP Surveys, the medically allowable error associated with the new test is within the standards accepted by the medical community. Thus, the safety and effectiveness of the new i-STAT Lactate test is established as substantially equivalent to that of a predicate device previously cleared for distribution and sale.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Paul VanDerWerf, Ph.D.
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i-STAT Corporation
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Re: K982071
i-STAT®¹ Lactate Test
Regulatory Class: I
Product Code: KHP
Dated: June 10, 1998
Received: June 12, 1998

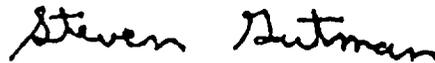
Dear Dr. VanDerWerf:

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 (Pre-market 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 pre-market 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) 594-4588. 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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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

III INDICATIONS FOR USE

510(k) Number (if known): K982071

Device Name: **Lactic Acid test.**

The i-STAT lactate test is useful for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

(Please do not write below this line—continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Per 21 CFR 801.109)

OR Over-The-Counter-Use

(Optional Format 1-2-96)

Carol C. Benson for Alfred Montoya

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K982071