K992684

JAN 14 2000

THERASENSE
The Technology of Caring

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 Not Assigned

1. Device Name

Classification Name: Glucose Test System (§ 862.1345)

Common/Usual Name: Blood Glucose Meter and Reagent Test Strips

Proprietary Names: FreeStyle™Blood Glucose Monitoring System

2. Legally Marketed Devices to which Substantial Equivalence is Claimed:

Predicate Device	510(k) number
FastTake	K970707
Accu-Chek Advantage with Comfort Curve Test Strips	K930979 K980731 K982002
AtLast	K982076

3. Device Description

The FreeStyle Blood Glucose Monitoring System comprises an electrochemical biosensor glucose reagent test strip, a handheld meter, a quality control solution, a complete Owner's

Booklet and a Quick Reference Guide. A lancing device, lancets and a logbook for recording test results are also included with the system.

When the user inserts a test strip, the meter turns on. The user acquires a blood sample (with the test strip in the meter) by picking up the meter and touching the edge of the test strip at the blood target area, filling the chamber on the strip by capillary action. The meter sounds a tone (beeps) to let the user know that the sample chamber is full and the reaction has begun. When the test is complete, the meter displays the glucose reading on its liquid crystal display (LCD).

4. Intended Use of the Device

The TheraSense FreeStyle Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh whole capillary blood. The FreeStyle System is intended for use outside the body (*in vitro* diagnostic use) by health care professionals and people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and it is not intended for use on neonates or with arterial blood samples.

5. Principle of Operation

The user obtains a blood sample using a conventional lancing technique on the finger or arm. The user inserts a test strip into the meter, which turns the meter on. When the strip is touched to the blood drop, the sample chamber on the strip fills by capillary action in approximately 2 seconds. The blood sample volume required is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger or other areas of the body such as the arm. Test results are displayed in about 15 seconds. The time required to display test results varies depending on the blood glucose concentration (approximately 15 to 45

seconds).

The glucose in the blood sample reacts with the glucose dehydrogenase enzyme to yield gluconolactone, and produces a small electrical current. This current is measured by the FreeStyle meter and displayed as a glucose level.

6. Summary of Data Demonstrating Substantial Equivalence

Performance testing of the FreeStyle Blood Glucose Monitoring System demonstrated that the system meets the performance requirements for its intended use. Laboratory testing was conducted in accordance with FDA draft guidance "Review Criteria for Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology. The results demonstrate that the FreeStyle Blood Glucose Monitoring System satisfies all performance requirements.

A multi-center controlled clinical study was conducted to demonstrate accuracy and precision of the FreeStyle System when used by lay users with diabetes mellitus and by experienced technicians. Blood glucose results obtained with FreeStyle and with the predicate device, Fast*Take* were compared to a standard laboratory test for measuring blood glucose.

The clinical data demonstrate that the performance of FreeStyle correlates well with the laboratory method. When the blood glucose results were analyzed by the Clarke Error Grid Analysis, the System produced results within the range of clinical acceptable accuracy. The data also demonstrate that the FreeStyle performs equivalently to the predicate device, Fast*Take*. The data also demonstrate that the system performs equivalently in the hands of the lay user and a trained technician.

7. Conclusions Drawn from Nonclinical and Clinical Tests

Laboratory and clinical studies demonstrate that the TheraSense FreeStyle Blood Glucose Monitoring System is equivalent to the *FastTake* Blood Glucose Monitoring System and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

Eva A. Conner, Ph.D.
Vice President, Quality Assurance/Regulatory Affairs
Therasense, Inc.
1360 South Loop Road
Alameda, California 94502

Re: K992684
Trade Name: FreeStyle™ Blood Glucose Monitoring System
Regulatory Class: II
Product Code: LFR
Dated: November 8, 1999
Received: November 9, 1999

Dear Dr. Connor:

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.

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/dsma/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

INDICATIONS FOR USE STATEMENT

510(k) Number: K992684

Device Name: FreeStyle™ Blood Glucose Monitoring System

Indications for Use:

The TheraSense Inc. FreeStyle™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh whole capillary blood. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. The FreeStyle™ System is intended for use outside the body (*in vitro* diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates (newborns) or arterial blood.

The FreeStyle Blood Glucose Monitoring System is specifically indicated for use on the finger or arm.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992684

(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 Uses ✓

(Per 21 CFR 801.109)