DEC 0 5 2001

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: K012014

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
FreeStyle Blood Glucose Monitoring System	K992684, K994433

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, a Quick Reference Guide and a "Getting Started" 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 sample 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 from the forearm, upper arm, finger, hand, calf or thigh. 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, thigh, and hand. 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

This 510(k) included changes to the product labeling to add precautions and information about alternative site testing. There are no changes to the product or the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 5 2001

Eve A. Conner, Ph. D.
Vice President, Quality Assurance and Regulatory Affairs
Therasense, Inc.
1360 South Loop Road
Alameda, CA 94502

Re: k012014
Trade/Device Name: FreeStyle™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR
Dated: November 5, 2001
Received: November 6, 2001

Dear Dr. Conner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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: 012014

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 whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

The FreeStyle Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

Susan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012014

(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 801.10)