THERASENSE
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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 Not Assigned

1. Sponsor's Name, Address, Telephone Number and Contact Person

Sponsor: TheraSense, Inc
1360 South Loop Road
Alameda, CA 94502

Contact Person: Eve A. Conner, Ph.D.
Telephone: (510) 749-5406
Facsimile: (510) 749-5401

2. Device Name

Classification Name: None[1,2]

Common/Usual Name: Data Management Software

Proprietary Names: FreeStyle™ Connect Data Management System

[1] The FreeStyle™ Connect Data Management System is considered an "unclassified" accessory to a blood glucose test system, Product Code 75LFR, Glucose Dehydrogenase.

[2] The device regulation for a "calculator/data processing module for clinical use", 21 CFR 862.2100, exempts such Class I devices from 510(k) Premarket Notification requirements. However, this regulation applies to data processors for clinical laboratory use, not home use. The regulation for the parent device (blood glucose monitor, Class II) is 21 CFR 862.1345, glucose test system.

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

Predicate Device	510(k) number
MediSense Precision Link Data Management System	K952279

4. Intended Use of the Device

The TheraSense FreeStyle™ Connect Data Management System is intended for use in home and clinical settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program.

5. Device Description

The FreeStyle™ Connect Data Management System is an optional data management software accessory for use with the FreeStyle™ Blood Glucose Monitoring System. The FreeStyle™ Connect Data Management System permits the transfer of data from the FreeStyle™ Blood Glucose Meter to a personal computer for enhanced data management capability.

6. Principle of Operation

The FreeStyle™ Blood Glucose Connect Data Management System retrieves each blood glucose test result and the date and time of the measurement from the memory of the FreeStyle™ Blood Glucose Meter via a direct serial cable connection between the Freestyle™ Meter and the personal computer.

The FreeStyle™ Blood Glucose Data Management Software operates in a Microsoft® Windows Operating System platform. The FreeStyle™ Blood Glucose Data Management Software creates a patient record in the database to

store the transmitted data or adds new data to an existing record. The FreeStyle™ Blood Glucose Data Management Software allows the user to display a variety of graphs and statistics based on user-selectable date intervals, time of day segments, blood glucose target ranges. The FreeStyle™ Connect Data Management System stores the patient data, patient-specific time of day segments, and patient-specific blood glucose target ranges in the patient file.

7. Summary of Data Demonstrating Substantial Equivalence

Software for the FreeStyle™ Connect Data Management System has been developed, verified and will be fully validated in accordance with TheraSense Inc. Software Development Procedures. In addition, the FreeStyle™ Connect Data Management System software has been developed in accordance with the FDA's Guide on the *Review of 510(k)s for Computer Controlled Medical Devices* (1991), *Guidance for the Content of Premarket Submission for Medical Devices Containing Software* (May 29, 1998) and *General Principles of Software Validation* (draft, 1997), where applicable and appropriate. Software verification testing demonstrates that the FreeStyle™ Connect Data Management System meets the performance requirements for the intended use of the device. Software Verification and Validation testing will be completed and the results will conform to the functional requirements specified in the software specifications before the FreeStyle™ Connect Data Management System will be released for commercial distribution.

8. Conclusions

Software verification testing demonstrates that the TheraSense FreeStyle™ Connect Data Management System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2000

Eva A. Connor, Ph.D.
Vice President
Quality Assurance and Regulatory Affairs
TheraSense Inc.
1360 South Loop Road
Alameda, California 94502

Re: K994433
Trade Name: FreeStyle™ Connect Data Management System
Regulatory Class: II
Product Code: LFR
Dated: April 5, 2000
Received: April 6, 2000

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.

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 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: ~~Not Assigned~~ K994433

Device Name: FreeStyle™ Connect Data Management System

Indications for Use:

The TheraSense Inc. FreeStyle™ Connect Data Management System is intended for use in home and clinical settings to aid people with diabetes and health care professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994433

(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)