



# New Device Clearance

## TheraSense, Inc. FreeStyle Tracker™ Diabetes Management System - K020866

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**Product Name:** FreeStyle Tracker™ Diabetes Management System

**Manufacturer:** TheraSense, Inc.

**Address:** 1360 South Loop Road, Alameda, CA 94502-7000

**Clearance Date:** June 11, 2002

**510(k) Statement:** <http://www.fda.gov/cdrh/pdf2/k020866.pdf>

**What is it?** The FreeStyle Tracker™ uses new technology for diabetes management by combining a glucose meter with a hand-held computer (also called a personal digital assistant or PDA). Together, these create a glucose meter that also tracks and helps manage blood sugar (glucose) levels.

**How does it work?** PDAs are small, hand-held electronic organizers based on computer technology. They let users store and retrieve phone numbers, appointments, and notes. All models can exchange information with personal computers. Some PDAs have expansion slots to attach cartridges (modules) for special functions.

The FreeStyle Tracker™ uses a Handspring Visor™ PDA, which is purchased separately. When a glucose module is inserted into its expansion slot, the PDA gives instructions for testing blood sugar and displays the results on its screen.

To use the system, the patient inserts a test strip into the glucose module, pierces the skin with a lancet, and places a drop of blood on the test strip. In addition to showing current blood sugar levels, the system stores readings in an electronic database. This database can also include insulin usage, food intake, exercise, and medicine. These data can be graphed and displayed on the PDA, or they can be uploaded to a personal computer (PC).

This system does not require a doctor's prescription.

**When is it used?** The FreeStyle Tracker™ is used by people with diabetes to measure glucose levels and track changes over time. It can be used by anyone who performs self-monitoring of blood glucose.

**What will it accomplish?** This device will help people with diabetes measure and manage their blood sugar levels. It will also help patients share details about their blood sugar levels with their healthcare providers. Studies have shown that patients who can control their blood glucose levels and who work closely with their healthcare providers have fewer diabetes complications such as heart disease, stroke, vision loss, amputation, and kidney disease.

**When should it not be used?** The FreeStyle Tracker™ Diabetes Management System should not be used without consulting a health care provider. This system only works with a Handspring Visor™ PDA; it cannot be used with other types of PDAs. Before relying on this system, patients should know how to use and install software on a PDA.

**Additional information:**

Other:

- FDA Diabetes Information: <http://www.fda.gov/diabetes>

[[Accessibility](#)]

*(Updated 7/12/2002)*