



New Device Approvals



GlucoWatch G2 Biographer -

P990026/S008

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: GlucoWatch G2 Biographer
Manufacturer: Cygnus, Inc.
Address: 400 Penobscot Drive, Redwood City, CA 94063
Approval Date: August 26, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/P990026S008a.pdf>

What is it? The GlucoWatch G2 Biographer is a blood sugar (glucose) monitoring device that is worn on the wrist like a watch and does not require drawing blood through a finger-stick. The device takes non-invasive glucose measurements through the skin every 10 minutes for up to 13 hours at a time. These readings are used to supplement finger-stick measurements in detecting and tracking patterns in glucose levels. The device should not be used as a substitute for finger-stick measurements.

The GlucoWatch G2 Biographer was originally approved by FDA for adult use in March, 2001. It is now also approved for use in children aged 7 or older. It is a prescription device that must be used under the care of a doctor.

How does it work? After a 2-hour warm-up period, patients calibrate the GlucoWatch G2 Biographer with a finger-stick measurement. After calibration, the device begins monitoring glucose. Batteries produce a small electrical current that pulls fluid through the skin and into the device. Then sensors (electrodes) measure the glucose in the fluid. The GlucoWatch G2 Biographer contains a built-in alarm that can be programmed to alert the user when results fall above or below pre-set levels.

When is it used? The GlucoWatch G2 Biographer is used together with traditional finger-stick measurements to provide additional glucose information to adults and children with diabetes and their healthcare providers.

What will it accomplish? Additional information on glucose trends and patterns may help people with diabetes and their healthcare providers manage their disease better than if they relied on finger-stick measurements alone.

When should it not be used? The GlucoWatch G2 Biographer should not be used:

- in patients who did not receive a prescription from a doctor who has completed a formal GlucoWatch training program;
- in patients who did not complete a formal GlucoWatch training program;
- in place of a blood glucose meter (treatment decisions should not be made or changed based on GlucoWatch G2 Biographer results alone);
- by children under 7 years of age.

Additional information: Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/P990026S008.html>

Other:

- FDA Talk Paper: <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00830.html>
- FDA Diabetes Information: <http://www.fda.gov/diabetes>
- American Diabetes Association: <http://www.diabetes.org>
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH: <http://www.niddk.nih.gov/health/diabetes/diabetes.htm>
- GlucoWatch information from NIH: <http://www.niddk.nih.gov/health/diabetes/dateline/fall00/3.htm>
- Directory of Diabetes Organizations: <http://www.niddk.nih.gov/health/diabetes/pubs/diaborgs/diaborgs.htm>

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