

JAN 21 1997

page 1 of 2

**510(k) SAFETY AND EFFECTIVENESS SUMMARY**

**Prepared:** August 30, 1996

**Submitter:** Bayer Corporation, Business Group Diagnostics

**Address:** 1884 Miles Avenue, P. O. Box 70  
Elkhart, IN 46515  
(219) 262-6929

**Contact:** Rosanne M. Savol, R.A.C.  
Manager, Regulatory Affairs

**Device:** Trade/Proprietary Name: **GLUCOMETER® DEX™ Diabetes Care System**  
Common/Usual Name: Test for glucose in blood  
Blood glucose meter  
Control material  
Document Control Number: K96\_\_\_\_\_

**Classification:** Division of Clinical Laboratory Devices  
Panel - Clinical Chemistry and Toxicology  
Classification Code - 75 CGA (Glucose Oxidase, Glucose)

**Predicate Devices:** **GLUCOMETER ELITE® Blood Glucose Monitoring System; YSI Model 2300 STAT Plus Analyzer; ACA® Discrete Clinical Analyzer; Hitachi 704 chemistry analyzer; Hitachi 747 chemistry analyzer.**

**Device Description:** The **GLUCOMETER DEX Diabetes Care System** consists of the **GLUCOMETER® DEX™ Blood Glucose Meter; GLUCOMETER® DEX™ Blood Glucose Test Sensor Disc; and the GLUCOMETER® DEX™ Controls (Normal, Low and High).** The **GLUCOMETER DEX Diabetes Care System** is an over-the-counter (OTC) home test for glucose in blood. It is for use by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

- Intended Use:** The GLUCOMETER DEX Diabetes Care System is for the self-monitoring of blood glucose as an adjunct to the care of persons with diabetes.\*
- Technological Characteristics:** The GLUCOMETER DEX Diabetes Care System employs an amperometric glucose oxidase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. The test sensor discs are individually sealed in a package of ten. Blood glucose results are referenced to plasma glucose. The System has a linear response to glucose from 10 - 600 mg/dL.
- Assessment of Performance:** The performance of the GLUCOMETER DEX Diabetes Care System was studied in-house and in clinical settings by healthcare professionals and by persons with diabetes. The studies demonstrated that users can obtain blood glucose results that are substantially equivalent to current methods for blood glucose.
- Conclusion:** The results of in-house and clinical evaluations of the GLUCOMETER DEX Diabetes Care System demonstrate that the device is equivalent in performance to the predicate devices and suitable for its intended use.

---

\* "Consensus Statement on Self-Monitoring of Blood Glucose," *Diabetes Care*, Vol. 10, No. 1, January-February 1987, pp. 95-99.