

K964004

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

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Device: Trade/Proprietary Name: **GLUCOMETER ENCORE® Blood
Glucose Test Strips (Modified)**
Common/Usual Name: **Test for glucose in blood**
Document Control Number: **K96 _____**

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 CFR (Hexokinase, Glucose)

Predicate Devices: **GLUCOMETER ENCORE Blood Glucose Test Strips
ACCU-CHEK® ADVANTAGE™ H Blood Glucose System
(Boehringer Mannheim Corporation)**

Device Description: **GLUCOMETER ENCORE Blood Glucose Test Strips are over-the-counter home tests for glucose in blood. They are for use by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. GLUCOMETER ENCORE Blood Glucose Test Strips are for use with GLUCOMETER ENCORE® Blood Glucose Meters.**

Intended Use: **GLUCOMETER ENCORE Blood Glucose Test Strips are for the self-monitoring of blood glucose as an adjunct to the care of persons with diabetes***

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

**Technological
Characteristics:**

GLUCOMETER ENCORE Blood Glucose Test Strips are specific for glucose and have been referenced to give plasma/serum glucose values. The test provides a quantitative measurement of glucose in whole blood from 10 to 600 mg/dL (0.6 to 33.3 mmol/L). The GLUCOMETER ENCORE whole blood glucose test is based on the hexokinase method using dry reagent technology.

**Assessment of
Performance:**

GLUCOMETER ENCORE Blood Glucose Test Strips were used with the GLUCOMETER ENCORE® QA+ and GLUCOMETER ENCORE® QA Blood Glucose Meters to evaluate the performance of the systems with arterial whole blood specimens. The evaluation was carried out in the STAT Laboratories of a large U.S. medical center. Fresh arterial specimens collected from catheters and deep sticks were used. The performance of the two GLUCOMETER ENCORE Systems was compared to the Accu-Chek® Advantage™ H Blood Glucose Meter and to other laboratory methods for the determination of glucose. The GLUCOMETER ENCORE Systems gave glucose results which compared well with the performance of the predicate and other comparative methods.

Conclusion:

The results of the clinical evaluation of GLUCOMETER ENCORE Blood Glucose Test Strips used with the GLUCOMETER ENCORE QA+ and GLUCOMETER ENCORE QA Blood Glucose Meters on arterial blood specimens demonstrated that the device is equivalent in performance to the predicate device and suitable for use with arterial blood specimens.