



SEP 5 1996

510(k) Summary

Manufacturer: Selfcare, Inc.
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Device Name: Elect Blood Glucose Monitoring System

Common Name: Blood glucose meter and reagent test strips for blood glucose

Classification: Class II as per 21 CFR 862.1345. Glucose test system; Code 75 CGA (Glucose oxidase, glucose)
Classification panel - clinical chemistry

Equivalent Devices: Precision QID Blood Glucose Monitoring System
Glucometer Elite Diabetes Care System

Product Description

The Elect Blood Glucose Monitoring System comprises a glucose reagent test strip, a amperometric meter and a quality control solution. The user inserts a test strip in the Elect Meter and applies a small drop of blood from a fingerstick to the sample point on the strip. The meter measures the electrical current that is generated which is proportional to the concentration of glucose present in the blood sample. The blood glucose result is displayed in 20 seconds. The system is calibrated to give a result equivalent to a plasma value, the measurement used by most clinical laboratories.

Intended Use:

The Elect Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Elect System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor effectiveness of diabetes control.

Substantial Equivalence:

The Elect Blood Glucose Monitoring System is similar in technological characteristics, methodology and intended use to the predicate devices listed above. The Elect System utilizes similar biosensor methodology based on a standard enzymatic methodology employing the enzyme glucose oxidase coupled to an electrochemical detection system to measure glucose levels in whole blood.