

JUN 20 1997

**510(k) Summary**

**Manufacturer:** Selfcare, Inc.  
200 Prospect Street  
Waltham, MA 02154  
Telephone: (617) 647-3900  
Fax: (617) 647-3939

**Contact Person:** Carol Adiletto

**Date:** February 25, 1997

**Device Name:** Elect II Blood Glucose Monitoring System

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

**Classification (meter/strips):** Class II as per 21 CFR Section 862.1345  
Glucose test system; Code 75 CGA  
(glucose oxidase, glucose)  
Classification panel - Clinical Chemistry

**Classification (control):** Class I as per 21 CFR Section 862.1660,  
Code 75 JJX (single analyte control)

**Classification (lancets):** Class I as per 21 CFR Section 878.4800,  
Code 79 FMK (lancet, blood)

**Performance Standards:** None established under section 514

**Equivalent Devices:** Elect Blood Glucose Monitoring System  
(Selfcare, Inc. K961985)

Precision Q.I.D. Blood Glucose Monitoring System  
(Medisense, Inc. K945887)

**Product Description:**

The Elect II 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 II 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 15 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 II Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Elect II 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 II Blood Glucose Monitoring System is similar in technological characteristics, methodology and intended use to the predicate devices listed above. The Elect II 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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Carol A. Adiletto, M.S.  
• Clinical Director  
SelfCare, Inc.  
200 Prospect Street  
Waltham, Massachusetts 02154

Re: K970707  
Elect II Blood Glucose Monitoring System  
Regulatory Class: II  
Product Code: CGA  
Dated: February 25, 1997  
Received: February 26, 1997

Dear Ms. Adiletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Indications for Use Form

510(k) Number (if known): K970707

Device Name: Elect II Blood Glucose Monitoring System

Indication for Use:

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

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K970707

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation

Prescription Use

OR

Over-The-Counter Use

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