

Section 5

**510(k) SUMMARY
(Summary of Safety and Effectiveness)**

Submitted by:

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Summary Prepared:

March 27, 1999

Name of the device:

Excel™ GE Blood Glucose Test Strips and Code Strip

Classification name(s):

Excel™ GE Blood Glucose Test Strips are a Class II device (21 CFR § 862.1345) for home use

Classification of predicate device(s):

Excel™ GE Blood Glucose Test Strips and Code Strip are not materially different from the predicate device, Glucometer Elite® Blood Glucose Test Strips and Code Strip. The predicate device is distributed by Bayer and was cleared for use in the United States by K964630, K951537 and K924499.

Description of the device/intended use(s):

Excel™ GE Blood Glucose Test Strips quantitatively measure glucose in fresh capillary whole blood and give results that are comparable to laboratory methods. They are intended for *in vitro* diagnostic (external) use by people with diabetes for self-monitoring of blood glucose. The Excel™ GE Blood Glucose Test Strips are designed to be used with Glucometer Elite® Blood Glucose Meters only.

Statement of How the Technological Characteristics of the Device Compare to the Predicate device:

The technological characteristics of both devices are the same since they are electrochemical devices that quantitatively measure glucose amperometrically and have the same safety and effectiveness. They have the same intended use, i.e. use by people with diabetes for self-monitoring of blood glucose. The new device is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Excel™ GE Blood Glucose Test Strips and Code Strip are intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Summary of Performance Data:

Laboratory and clinical studies demonstrate that the Excel™ GE Blood Glucose Test Strips and Code Strip for use with Glucometer Elite® Blood Glucose Meters provides equivalent performance to the Glucometer Elite® Blood Glucose Test Strips and Code Strip for use with Glucometer Elite® Blood Glucose Meters.

Precision: A laboratory study of 20 samples (n=20), using Excel™ GE Blood Glucose Test Strips and Glucometer Elite® glucose meters to test whole blood samples at 4 different glucose levels (Glucose Level), showed the following performance:

Precision	Elite® Model 3901A				Elite® Model 3901M				
	Glucose Level	n	mean glucose (mg/dL)	SD (mg/dL)	CV (%)	n	mean glucose (mg/dL)	SD (mg/dL)	CV (%)
	1	20	47	1.2	2.6	20	43	1.2	2.7
	2	20	77	2.3	3.0	20	83	2.2	2.7
	3	20	145	3.2	2.2	20	160	3.6	2.2
	4	20	360	6.4	1.8	20	331	7.0	2.0

Accuracy	Elite® Model 3901A	Elite® Model 3901M
Accuracy of Professional users compared to YSI using capillary whole blood on 128 patients with diabetes at three clinical centers	n = 252 y = 0.91x + 0.18 r = 0.9877 Sy.x = 11.45 Range = 51 – 374 mg/dL	n = 253 y = 0.93x + 1.24 r = 0.9949 Sy.x = 7.55 Range = 51 – 374 mg/dL
Accuracy of Lay users compared to YSI using capillary whole blood on 128 patients with diabetes at three clinical centers	n = 128 y = 0.92x + 6.99 r = 0.9883 Sy.x = 11.38 Range = 51 – 374 mg/dL	n = 128 y = 0.95x + 3.92 r = 0.9941 Sy.x = 8.31 Range = 51 – 374 mg/dL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 1999

Ms. Carol Adiletto
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453-3457

Re: K991480
Trade Name: Excel™ GE Blood Glucose Test Strips and Code Strip
Regulatory Class: II
Product Code: CGA
Dated: August 9, 1999
Received: August 11, 1999

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 legally marketed predicate 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 (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 premarket 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.

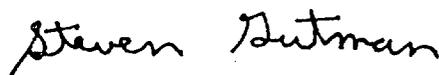
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K 991480

Device Name: Excel™ GE Blood Glucose Test Strips and Code Strip

Indications for Use:

Excel™ GE Blood Glucose Test Strips quantitatively measure glucose in fresh capillary whole blood and give results that are comparable to laboratory methods. They are intended for *in vitro* diagnostic (external) use by people with diabetes for self-monitoring of blood glucose. The Excel™ GE Blood Glucose Test Strips are designed to be used with Glucometer Elite® Blood Glucose Meters only.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 991480

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.019)

OR

Over-The-Counter Use