4/20/99

K990935

Section 10

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

Submitted by:

Carol A. Adiletto
Director of Clinical Affairs
Selfcare, Inc.
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Contact Person:

Carol A. Adiletto
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Summary Prepared:

March 19, 1999

Name of the device:

Fast*Take*® Compact Blood Glucose Monitoring System

Classification name(s):

The Fast*Take*® Compact Blood Glucose Monitoring System is classified as a Class II device (21 CFR § 862.2100). It is for home use.

Classification of predicate device(s):

The Fast*Take*® test strip of the Fast*Take*® Compact Blood Glucose Monitoring System is being modified to provide a visual confirmation window to provide the user with a way of ensuring that sufficient blood has been applied to the test strip.

The Fast*Take*® Compact Blood Glucose Monitoring System which is not materially different from the predicate device, Fast*Take*® Compact Blood Glucose Monitoring System, was cleared for use in the United States as the Elect II Blood Glucose Monitoring System by K970707. Both the modified and unmodified Fast*Take*® Blood Glucose Monitoring Systems were developed and are controlled Selfcare, Inc. in Waltham, MA. LifeScan, Inc. of Milpitas, CA distributes the Fast*Take*® Compact Blood Glucose Monitoring System.

Description of the device

The Fast*Take*® system includes four main components:

- Fast*Take*® Test Strips
- Fast*Take*® Compact Blood Glucose Meter
- Fast*Take*® Control Solution
- Penlet II or Penlet Plus lancing device and FinePoint lancets.

Intended use(s):

The Intended Use of the Fast*Take*® Compact Blood Glucose Monitoring System is the same as the device that was cleared by K970707.

The Fast*Take*® Compact Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Fast*Take*® 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.

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

The technological characteristics of the modified Fast*Take*® Compact Blood Glucose Monitoring System are the same as the legally marketed predicate device (unmodified Fast*Take*® Compact Blood Glucose Monitoring System).

Summary of Performance Data:

Verification and validation tests demonstrate that modified Fast*Take*® Compact Blood Glucose Monitoring System has equivalent performance to the unmodified Fast*Take*® Compact Blood Glucose Monitoring System.

The Fast*Take*® strips with the new confirmation window feature were evaluated in a consumer-use study by 19 diabetic patients who ranged in age from 3 to 54.

The results of this study indicate that typical intended users (i.e. people with diabetes) can use the new Fast*Take*® strips' confirmation window to view sample filling adequacy. The data showed that the patients detected under-filled and correctly filled strips with 99% accuracy. The ability of individual patients to test independently was also demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 20 1999

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

Re: K990939
Trade Name: Fast*Take*® Compact Blood Monitoring System
Regulatory Class: II
Product Code: CGA
Dated: March 19, 1999
Received: March 22, 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.

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 Gutman

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 Labeling and "Indications for Use" Statement

4.1 ODE INDICATIONS STATEMENT

Indications for Use Statement

510(k) Number (if known): K990939

Device Name: Fast*Take*® Compact Blood Glucose Monitoring System

Indications for Use:

The Fast*Take*® Compact Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The Fast*Take*® 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.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory ...
510(k) Number K990939

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** Over-The-Counter Use ✓
(Per 21 CFR 801.019)