K983468

DEC 17 1998

Section 5
510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

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Director of Quality and Regulatory Affairs
Selfcare, Inc.
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Contact Person:

Betty Lane
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Summary Prepared:

September 30, 1998

Name of the device:

Fast*Take*® Adapter

Classification name(s):

The Fast*Take* Adapter is a Class I accessory device classified as a calculator/data processing module for clinical use (21 CFR § 862.2100). As it can also be used in the home by a layperson, it is not exempt from premarket notification (21 CFR § 862.9(a)).

Classification of predicate device(s):

The Fast*Take* Adapter is not materially different from the predicate device, the Precision Link™ Communications Box, a component of the Precision Link™ Blood Glucose Data Management System. The predicate device is manufactured by Medisense, Inc and was cleared for use in the United States by K952279. The Precision Link™ System, which is classified as a data management system, is comprised of five separate components: data management software, communications box, an AC power adapter, communications cable, and an RS-232 cable. It is the Precision Link™ Communications Box that the Fast*Take* Adapter is analogous to. Whereas K952279 covered all components of the Precision Link™ Data Management System, this premarket notification covers only the communication link component (i.e. the Fast*Take* Adapter).

Description of the device/intended use(s):

The Fast*Take*® Adapter is an accessory to the Fast*Take* Blood Glucose Meter. It provides a communication link between the Fast*Take* Meter and the ONE TOUCH® cable, neither of which is included with the Adapter. The Fast*Take* Adapter is intended to be used for data transfer between a Fast*Take* Meter and a personal computer.

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

The technological characteristics are the same as both devices are micoprocessor controlled communication devices, thus have the same safety and effectiveness. They have the same intended use, i.e. communication between a PC and a glucose meter.

Summary of Performance Data:

Software and hardware verification and validation tests demonstrate that the FastTake Adapter provides reliable communication between a PC and the FastTake Blood Glucose Meter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 1998

Ms. Betty J. Lane
Director of Quality and
Regulatory Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453-3457

Re: K983468
Trade Name: Fast*Take*® Adapter
Regulatory Class: I
Product Code: JQP
Dated: September 30, 1998
Received: October 1, 1998

Dear Ms. Lane:

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.

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

Indications for Use Statement

510(k) Number (if known): K983468

Device Name: Lifescan Fast*Take*® Adapter

Indications for Use:

The Lifescan Fast*Take*® Adapter is an accessory to the Lifescan Fast*Take*® Blood Glucose Meter. It provides a communication link between the Fast*Take*® Meter and the Lifescan ONE TOUCH® Interface cable, neither of which is included. The Fast*Take*® Adapter is intended to be used for data transfer between a Fast*Take*® Meter and a personal computer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983468

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