K984261

MAY 21

510(k) Summary
Summary of Safety and Effectiveness

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95037
Contact	James Phelps/Roger Thies Hyman, Phelps, and McNamara
Date	11/25/98
Proprietary Name	LifeScan SURESTEP® Blood Glucose Monitoring System
Common Name	Blood Glucose Monitor
Classification	75CGA: glucose oxidase, glucose test system

Device Description
The SURESTEP Blood Glucose Monitoring System consists of a glucose reagent test strip, a reflectance photometer and quality control materials and may include data transfer or management hardware and/or software tools.

Intended Use
The SURESTEP Blood Glucose Monitoring System is intended for quantitative measurement of glucose in a sample of whole blood. It can be used by lay persons for capillary blood glucose monitoring in the home. It can also be used by healthcare professionals in a clinical setting to measure glucose in arterial, venous and capillary samples in both adults and neonates.

Substantial Equivalence
The LifeScan SURESTEP Blood Glucose Monitoring System is substantially equivalent to the original SURESTEP Blood Glucose Monitoring System, K942455, and the SURESTEPPRO Blood Glucose Monitoring System, k970556.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 1999

LifeScan
c/o James R. Phelps
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005

Re: K984261
Trade Name: LifeScan SureStep® Blood Glucose Monitoring System
Regulatory Class: II
Product Code: CGA
Dated: May 14, 1999
Received: May 17, 1999

Dear Mr. Phelps:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

Statement of Intended Use

Device Name: LifeScan SureStep® Blood Glucose Monitoring System

Indications for Use:
The LifeScan SureStep Blood Glucose Monitoring System is intended for quantitative measurement of glucose in a sample of whole blood. It can be used by lay persons for capillary blood glucose monitoring in the home. It can also be used in a clinical setting to measure glucose in arterial, venous, and capillary samples in both adults and neonates.

Lisa M Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984261

Prescription Use ____ OR Over-The Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)