April 29, 1999

K984527

510(k) Summary

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035
Contact Person	Lori D. Conzen Sr. Regulatory Affairs Specialist Tel: (408) 942-5606 Fax: (408) 942-5906
Date	December 18, 1998
Proprietary Name	IN TOUCH® Diabetes Management Software
Common Name	Data Management Software
Classification No. and Name	None[1]
Regulation No.	None[2]

Device Description

The IN TOUCH Diabetes Management Software System is an optional data management software accessory for use with LifeScan Brand blood glucose monitors such as the ONE TOUCH®, SureStep® and Fast*Take*® Meters. When used with one of these meters, IN TOUCH permits the transfer of data from the glucose meter memory into a computer for enhanced data management capability.

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[1] IN TOUCH is considered an "unclassified" accessory to a blood glucose test system, Classification Number 75CGA, Glucose oxidase, glucose.

[2] The device regulation for a "calculator/data processing module for clinical use" (862.2100) exempts such Class I devices from 510(k) Premarket Notification requirements. This regulation is not entirely applicable to IN TOUCH, however, since this exemption only applies to data processors for clinical laboratory use, not home use. The regulation for the parent device (blood glucose monitor – Class II) is 862.1345, "glucose test system."

Intended Use

The IN TOUCH Diabetes Management Software is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management.

Substantial Equivalence

The IN TOUCH Diabetes Management Software System is substantially equivalent to the currently marketed LifeScan ONE TOUCH® Profile® Diabetes Tracking System and the MediSense® Precision Link™ Blood Glucose Data Management System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 29 1999

Ms. Lori D. Conzen
Senior Regulatory Affairs Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, California 95035

Re: K984527
Trade Name: IN TOUCH® Diabetes Management Software
Regulatory Class: II
Product Code: CGA
Dated: April 9, 1999
Received: April 12, 1999

Dear Ms. Conzen:

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

Indications for Use Statement

510(k) Number (if known): K984527

Device Name: IN TOUCH® Diabetes Management Software System

Indications for Use:

The IN TOUCH Diabetes Management Software System is intended for use in home and clinical settings to aid people with diabetes and health care professionals in the review, analysis, and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to LifeScan Brand blood glucose monitoring systems with data management capabilities.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984527

(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 801.109)

(Optional Format 1-2-96)