

JAN 26 1998

### 510(k) Summary

**Submitter** LifeScan, Inc.  
1000 Gibraltar Drive  
Milpitas, CA 95035

**Contact Person** Lori D. Conzen  
Regulatory Affairs Specialist  
Tel: (408) 942-5606  
Fax: (408) 942-5906

**Date** November 13, 1997

**Proprietary Name** ONE TOUCH® II Hospital Blood Glucose  
Monitoring System  
ONE TOUCH® II Test Strips (Hospital Products)

**Common Name** Blood Glucose Monitoring System

**Classification Name** 862.1345, Glucose test system  
75CGA Glucose oxidase, glucose

#### Device Description

The ONE TOUCH® II Hospital Blood Glucose Monitoring System consists of a reagent test strip, a portable, hand-held, battery operated, electronic reflectance photometer (meter) and ancillary devices. The test method employs a dry reagent technology based on the glucose oxidase method and is specific to D-glucose. The intensity of the blue color produced on the strip after applying a drop of whole blood to the ONE TOUCH® Test Strip correlates with the level of glucose in the whole blood sample. The meter measures the reflectance of the reacted test strip at specific wavelengths and displays the corresponding whole blood glucose value or converts the reading to an approximate plasma/serum glucose equivalent.

### **Intended Use**

The ONE TOUCH® II Hospital Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in whole blood when monitoring blood glucose levels in hospitals, clinics, and in home settings. ONE TOUCH® Test Strips may be used with the ONE TOUCH® II Hospital Meter to monitor neonates for hypoglycemia in hospital, clinic and home settings. Non-neonatal whole blood glucose measurements may also be reported in terms of approximate plasma/serum equivalents.

### **Substantial Equivalence**

The system manual for ONE TOUCH® II Hospital Blood Glucose Monitoring System and the package insert for the ONE TOUCH® Test Strips (Hospital Products) have been modified to identify arterial whole blood as a suitable sample and incorporate summaries of studies demonstrating arterial sample suitability in addition to necessary precautions. No changes to existing technology were required for implementation, so the "substantial equivalence" of the ONE TOUCH® II Hospital Blood Glucose Monitoring System is unaffected.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 26 1998

Lori D. Conzen  
Regulatory Affairs Specialist  
LifeScan, Inc.  
1000 Gibraltar Drive  
Milpitas, California 95035-6312

Re: K974451  
ONE TOUCH® II Hospital Blood Glucose Monitoring System  
Regulatory Class: II  
Product Code: CGA  
Dated: November 24, 1997  
Received: November 25, 1997

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 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 (Pre-market 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.

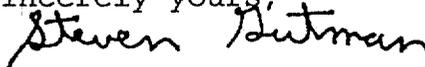
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

### Indications for Use Statement

510(k) Number (if known): 974451

Device Name: ONE TOUCH® II Hospital Blood Glucose Monitoring System

#### Indications for Use:

The ONE TOUCH® II Hospital Blood Glucose Monitoring System, consisting of the ONE TOUCH® II Hospital Meter, ONE TOUCH® Test Strips (Hospital Products), control solutions, data management software and other optional accessories is intended for quantitative measurement of glucose in whole blood in hospital, clinic, and home settings. It is intended for monitoring glucose levels in neonatal and non-neonatal whole blood samples. Non-neonatal glucose results can be reported in either whole blood equivalents or plasma/serum equivalents.

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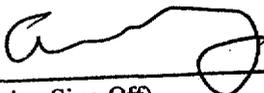
#### Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format I-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 974451