JUN 2 8 2002

K021943

510(k) SUMMARY
(As required by 21 C.F.R. § 807.92)

Submitted By:	Lifescan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035
Contact Person:	John E. Hughes Phone: 408–942–5903 Fax: 408–942–5906
Date Summary Prepared:	June 20, 2002
Device Name	ONETOUCH® Profile Meter
Classification	862.1345 Glucose Test System
Description of the Changed Labeling	The labeling of this device was modified to enhance instructions for use advising users to insure the display is operating properly each time they perform a test.
Statement of Intended Use:	The ONETOUCH Profile Meter is used for the quantitative determination of glucose in whole blood by lay persons in the home and by medical professionals in clinical settings as an aid in monitoring effectiveness of diabetes management.
Substantial Equivalence:	The current labeling for this meter advises users to check that the display is operating properly. The revised labeling clarifies that the user should check the display integrity each time a test is performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 8 2002

Mr. John E. Hughes
Manager
Regulatory Submissions
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Re: k021943
Trade/Device Name: OneTouch® Profile Meter
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA
Dated: May 24, 2002
Received: May 28, 2002

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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: K021943

Device Name: **ONETOUCH® Profile Meter**

Indications for Use:

The ONETOUCH® Profile Meter is used for the quantitative measurement of glucose in whole blood by lay persons in the home and by medical professionals in clinical settings as an aid in monitoring effectiveness of diabetes management.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021943

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)