K024194

FEB 07 2003

510(k) Summary

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035 Contact: Mary Ellen Holden Date Prepared: December 19, 2002
Device Name	One Touch® Ultra® Blood Glucose Monitoring System Common name: Glucose test system Classification: Blood Glucose Meters and Test Strips are Class II devices (21 CFR Section 862.1345, Glucose Monitor)
Predicate Device	One Touch® Ultra® Blood Glucose Monitoring System

Device Description
The One Touch Ultra System consists of the One Touch Ultra Meter, One Touch Ultra Test Strips, One Touch Ultra Control Solution, UltraSoft Lancing Device, UltraClear Cap and UltraSoft lancets. The One Touch Ultra meter, when used with the One Touch Ultra Blood Glucose Test Strips, quantitatively measures glucose in capillary whole blood. The One Touch Ultra Control Solution verifies the performance of the One Touch Ultra Blood Glucose Test Strips.

Intended Use
The One Touch Ultra System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The One Touch Ultra System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Comparison to Predicate Device System
The modifications to the device system encompass meter software and labeling changes. There has been no change to the intended use, fundamental scientific technology, physical design, operating principles, functionality or material composition of the device systems.

Technological Characteristics
There has been no change to the fundamental scientific technology. The meter software changes have been verified.

Summary of Performance Characteristics
There has been no change to the performance characteristics of the device system.

Conclusion
The modified One Touch Ultra Blood Glucose Monitoring System is substantially equivalent to the predicate device system.

510(k) Summary

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035 Contact: Mary Ellen Holden Date Prepared: December 19, 2002
Device Name	One Touch® InDuo™ Blood Glucose Monitoring System Common name: Glucose test system Classification: Blood Glucose Meters and Test Strips are Class II devices (21 CFR Section 862.1345, Glucose Monitor)
Predicate Device	One Touch® InDuo™ Blood Glucose Monitoring System

Device Description
The One Touch InDuo System consists of the One Touch InDuo Meter (*which also functions as a cap for the InDuo Insulin Doser*), One Touch Ultra Test Strips, One Touch Ultra Control Solution, UltraSoft Lancing Device, UltraClear Cap and UltraSoft lancets. The One Touch InDuo meter, when used with the One Touch Ultra Blood Glucose Test Strips, quantitatively measures glucose in capillary whole blood. The One Touch Ultra Control Solution verifies the performance of the One Touch Ultra Blood Glucose Test Strips.

Intended Use
The InDuo Blood Glucose Meter is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The InDuo Blood Glucose Meter is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

The InDuo Blood Glucose Meter also functions as the cap for the InDuo Insulin Doser. The two devices fit together to form a single unit for user convenience.

Comparison to Predicate Device System
The modifications to the device system encompass meter software and labeling changes. There has been no change to the intended use, fundamental scientific technology, physical design, operating principles, functionality or material composition of the device systems.

Technological Characteristics
There has been no change to the fundamental scientific technology. The meter software changes have been verified.

Summary of Performance Characteristics
There has been no change to the performance characteristics of the device system.

Conclusion
The modified One Touch InDuo Blood Glucose Monitoring System is substantially equivalent to the predicate device system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 7 2003

Ms. Mary Ellen Holden
Senior Regulatory Submissions Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035

Re: k024194
Trade/Device Name: One Touch® InDuo™ Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: December 19, 2002
Received: December 20, 2002

Dear Ms. Holden:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K024194

Device Name: **ONE TOUCH® ULTRA® Blood Glucose Monitoring System**

Indications for Use:

The One Touch® Ultra® System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The One Touch® Ultra® System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024194

Concurrence of CDRH, Office of Device Evaluation

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

Indications for Use Statement

510(k) Number: K024194

Device Name: **ONE TOUCH® INDUO™ Blood Glucose Monitoring System**

Indications for Use:

The One Touch® InDuo™ Blood Glucose Meter is intended to be used for quantitative measurement of glucose in fresh capillary whole blood. The InDuo™ Blood Glucose Meter is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

The One Touch® InDuo™ Blood Glucose Meter also functions as the cap for the InDuo™ Insulin Doser. The two devices fit together to form a single unit for user convenience.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024194

Concurrence of CDRH, Office of Device Evaluation

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