

DEC 16 1997

510(k) Summary

Submitter LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95037
John E. Hughes

Date July 1, 1997

Proprietary Name ONE TOUCH® II Hospital Blood Glucose
Monitoring System
DataDock

Common Name Blood Glucose Monitor

Classification Name 75CGA Glucose oxidase, glucose

Device Description

The DataDock is an optional accessory for the ONE TOUCH® II Hospital Meter. When the ONE TOUCH® II Hospital Meter is inserted into the DataDock, it provides features which improve ease-of-use and enhance data management capability.

Intended Use

The ONE TOUCH® II HOSPITAL Blood Glucose Monitoring System, consisting of the ONE TOUCH® II Hospital Meter, ONE TOUCH® Test Strips, control solutions, data management software, and the DataDock 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 blood glucose levels in neonatal or non-neonatal whole blood samples. Non-neonatal blood glucose results can be reported in either whole blood equivalents or plasma/serum equivalents.

Substantial Equivalence

The DataDock is an optional accessory modifying the ONE TOUCH® II Hospital Blood Glucose Monitoring System currently in commercial distribution. The modification neither significantly changes the safety and effectiveness nor makes any change to its intended use of the device.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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John E. Hughes
Manager, Regulatory Affairs
LifeScan Inc.
1000 Gibraltar Drive
Milpitas, California 95035-6312

Re: K972473
ONE TOUCH II DataDock Hospital Blood Glucose
Monitoring System
Regulatory Class: II
Product Code: CGA
Dated: October 1, 1997
Received: October 3, 1997

Dear Mr. Hughes:

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 (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.

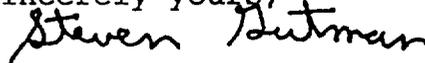
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

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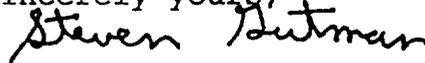
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Director
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Enclosure

Indications for Use Form

510(k) Number (if known) 972473

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

Indications for Use

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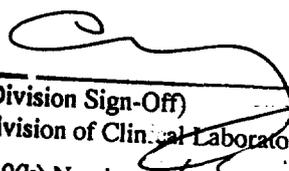
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 972473 134