MAY 1 5 2001

510(k) Control No. K 001699

510(k) Summary
Rubicon Prothrombin Time Monitoring System

Submitter	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95037 Contact: John E. Hughes Date of Preparation: September 29, 2000
Device Name	Rubicon™ Prothrombin Time Monitoring System Common Name: Prothrombin Time Test
Predicate Device	CoaguChek™ System for Prothrombin Time Self–Testing
Device Description	The Rubicon System consists of a Meter and Test Strip. When a drop of blood is placed on the test strip, the blood is drawn into the reaction cells and mixed with reagents that cause blood clotting to begin. The meter monitors the blood clotting process by passing a light beam through the blood sample being tested. The meter detects blood clot formation and, at the conclusion of the test, the prothrombin time is displayed in International Normalized Ratio (INR) units.
Intended Use	For quantitative determination of prothrombin time (PT) in capillary whole blood by properly selected and trained patients or their caregivers, or in capillary or venous whole blood by health care professionals, as an aid in monitoring oral anticoagulation therapy.
Comparison to Predicate Device	The Rubicon Prothrombin Time Monitoring System and the Roche Diagnostics CoaguChek System for Prothrombin Time Self–Testing both consist of a meter and disposable test strip. Both systems employ whole blood as a test sample and can be used to monitor oral anticoagulation therapy. Both employ thromboplastin to cause blood coagulation. The systems differ in that the Rubicon device detects clotting through changes in light transmission while the Roche product uses cessation of admixed iron particle motion, induced by an oscillating magnetic field, when clotting occurs. The CoaguChek system uses animal thromboplastin and liquid quality control materials while Rubicon depends upon recombinant human thromboplastin and dry quality control samples incorporated into the disposable. Performance of the two systems was compared on 217 normal and anticoagulated subjects (INR ranging from 0.8 to 6.0) at 3 sites. The regression equation relating results obtained with Rubicon (y) to those obtained with the CoaguChek (x) system was: $y = 1.02x - 0.07$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 15 2001

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

Re: 510(k) Number: K001699
Trade/Device Name: Rubicon Prothrombin Time Monitoring System
Regulation Number: 864.7750
Regulatory Class: II
Product Code: GJS
Dated: February 28, 2001
Received: March 1, 2001

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA, are required to conduct postmarket surveillance studies. The FDA believes that under Section 522(a) (2), discretionary postmarket surveillance will be in order for the ITC ProTime Microcoagulation Device. Please contact Michelle Y. Clark-Stuart at (301) 594-1243 within 30 days of receipt of this letter, to arrange a meeting to discuss the objectives and design of a future discretionary postmarket surveillance study.

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 at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/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

Indications for Use Statement

510(k) Number: K 001699-52
Name: Rubicon Prothrombin Time Monitoring System

Indications for Use

For quantitative determination of prothrombin time (PT) in capillary whole blood by properly selected and trained patients or their caregivers, or in capillary or venous whole blood by health care professionals, as an aid in monitoring oral anticoagulation therapy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 001699-52

Concurrence of CDRH, Office of Device Evaluation (ODE)

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