510(k) Summary

DEC 1 7 2008

SUBMITTER:

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Contact: Martha Murari, Ph.D., RAC
Sr. Regulatory Submissions Specialist

DEVICE NAME: Symphony Meter Remote

COMMON OR USUAL NAME: Remote Controller and Accessory for Insulin Infusion Pump

DEVICE CLASSIFICATION:

Classification of device used as Remote Controller and Accessory for Insulin Infusion Pump is as follows:
• Class II per 21 CFR § 880.5725, Pump, Infusion, Insulin (product code LZG)

Classifications of devices used with Glucose Test System of the Symphony Meter Remote are as follows:
• Class II, One® Touch Ultra® Test Strips, per 21 CFR § 862.1345 (product code CGA)
• Class I, OneTouch® Ultra® Control Solution, per 21 CFR § 862.1660 (product code JJK)
• Class I (exempt) OneTouch® Lancing Device with OneTouch® AST ClearCap™ and OneTouch® UltraSoft® Sterile Lancet, per 21 CFR § 878.4800 (product code FMK)

PREDICATE DEVICES:

The predicate device is as follows:
•Symphony Meter Remote previously filed as part of the Symphony Glucose Management System (K080639)

DEVICE DESCRIPTION:

The Symphony Meter Remote is designed to function both as an *in vitro* diagnostic device for self-monitoring blood glucose (measure blood glucose concentrations) and as a remote controller of a Symphony Pump for insulin delivery through an infusion set placed subcutaneously.

The Symphony Meter Remote is a reusable handheld-battery operated device supplied clean and non-sterile to primarily function as a stand-alone blood glucose meter. With user activation of RF communication between a specific Symphony Meter Remote and specific Symphony Pump, the Symphony Meter Remote also becomes a remote controller of certain features of the Symphony Pump. When paired through radio frequency (RF) communication

the Symphony Meter Remote can be used to control bolus insulin delivery, review the status of the Symphony Pump and view and confirm selected pump alerts and warnings.

The Symphony Meter Remote incorporates other design features that utilize glucose test data, insulin delivery data, and information important to overall diabetes management, as well as provide interface capability with a personal computer (PC) via data management software.

INTENDED USE/ INDICATIONS FOR USE:
The Symphony Meter Remote is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood, and as a wireless (RF) remote control to deliver insulin from the Symphony Pump. The Symphony Meter Remote is intended for use for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The Symphony Meter Remote is specifically indicated for use on the finger, forearm or palm. It should not be used for the diagnosis of diabetes or testing of newborns.

SUBSTANTIAL EQUIVALENCE:
As part of the Symphony Glucose Management System (K080639, cleared June 24, 2008), the Symphony Meter Remote remains the same as submitted with the system and remains substantially equivalent to the device submitted therein.

RESULTS OF PERFORMANCE EVALUATION:
Performance evaluations, both bench and clinical, of the Symphony Meter Remote were completed and did not raise any new issues of safety and effectiveness.

CONCLUSION:
The Symphony Meter Remote is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Martha Murari, Ph.D., RAC
Senior Regulatory submissions Specialist
LifeScan, Incorporated
1000 Gibraltar Drive
Milpitas, California 95035

DEC 17 2008

Re: K082590
Trade/Device Name: Symphony Meter Remote
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG, CGA
Dated: November 24, 2008
Received: November 25, 2008

Dear Dr. Murari:

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 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082590

Device Name:
Symphony Meter Remote

Indications for Use:

The Symphony Meter Remote is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood, and as a wireless (RF) remote control to deliver insulin from the Symphony Pump. The Symphony Meter Remote is intended for use for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The Symphony Meter Remote is specifically indicated for use on the finger, forearm or palm. It should not be used for the diagnosis of diabetes or testing of newborns.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082590