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K971014

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**510(k) Summary  
Summary of Safety and Effectiveness**

**Submitter** LifeScan, Inc.  
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Milpitas, CA 95035  
Judy Martin, RAC

**Date** March 18, 1997

**Proprietary Name** LifeScan SureStep®Pro Glucose Control  
Solutions (Low, Normal and High)  
  
LifeScan SureStep®Pro Linearity Test Kit

**Common Name** Single (specified) Analyte Control (Assayed)

**Classification Name** 21 CFR 862.1660, Quality Control Material  
(assayed and unassayed) - (75JJX)

**Device Description**

The SureStep®Pro Glucose Control and Linearity Test Solutions are designed for use with LifeScan SureStep® Brand Blood Glucose Meters and SureStep®Pro Brand Test Strips.

SureStep®Pro Glucose Control Solutions contain a measured amount of glucose that reacts with the SureStep®Pro Test Strips. When using the same procedure as testing with whole blood, the control solution should provide results within the expected SureStep®Pro Glucose Control Solution range printed on the test strip bottle. Obtaining results outside the expected range indicates the System is not performing correctly.

The SureStep®Pro Linearity Test Solutions contain a measured amount of glucose. When the linearity solution is applied to a SureStep®Pro Test Strip in the same manner as the glucose controls the results are used to verify System linearity.

## Intended Use

The intended use of the LifeScan SureStep®Pro Glucose Control Solutions and the currently marketed SureStep® Glucose (Normal) Control Solution is identical. The intended use for the SureStep®Pro Glucose Control Solutions is as follows:

*SureStep®Pro Glucose Control Solutions are for use with SureStep® Brand Blood Glucose Meters and SureStep®Pro Test Strips as a quality control material for verification of System performance.*

The intended use of the LifeScan SureStep®Pro Linearity Test Kit is equivalent to the Streck Sugar-Chex® Linearity kit with the exception that the SureStep®Pro Linearity Test Kit is not intended for calibration assessment. The intended use for the SureStep®Pro Linearity Test Kit is as follows:

*The SureStep®Pro Linearity Test Kit is for use with SureStep® Brand Glucose Meters and SureStep®Pro Test Strips for verification of System linearity.*

## Substantial Equivalence

The LifeScan SureStep®Pro Glucose Control Solutions (Low, Normal and High) and Linearity Test Kit are substantially equivalent to the currently marketed LifeScan SureStep® Glucose (Normal) Control Solution and Streck Laboratories Sugar-Chex® Linearity kit, respectively.