

K 962295

Summary of Safety and Effectiveness

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MediSense, Inc.
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- Device Name:** Precision QID™ Blood Glucose Test Strip
- Common Name:** Reagent test strips for Blood Glucose
- Classification:** "Glucose Test System" - Class II per CFR 862.1345
- Predicate Devices:** Precision QID™ Blood Glucose Test Strip - K945887
Accu-Chek Advantage Test Strips - K951887
- Description:** The Precision QID Blood Glucose Test Strip utilizes amperometric biosensor technology to quantitatively measure glucose in whole blood and control solutions. Insertion of a test strip into the sensor, automatically turns the sensor on. A drop of whole blood or control solution is applied to the target area of the test strip and the assay is automatically initiated. A countdown begins and glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface, generating a current that is measured by the Precision QID Sensor. The size of the current is proportional to the amount of glucose present in the sample, thus giving an accurate reading of glucose concentration after 20 seconds.
- Because the Precision QID Blood Glucose Test Strip is an evolutionary offspring of the MediSense Pen 2 / Companion 2 Blood Glucose Test Strip, the Precision QID Blood Glucose Test Strip is fully compatible with the Pen 2/ Companion 2 Test System (K901613), the Satellite G Test System (K891695) which has been renamed to Precision G, The MediSense 2 Pen and Card System (K944195), and the Precision QID Test System (K944195).
- Intended Use:** The Precision QID Blood Glucose Test Strips are intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. For home or professional use with the Precision QID Blood Glucose Sensor. Compatible with the MediSense 2 Card and Pen Blood Glucose Sensors, and the Companion 2 Card and Pen Blood Glucose Sensors.

The product may also be used by healthcare professionals for quantitative measurement of glucose in venous or arterial whole blood, provided the sample is used within 15 minutes.

Comparison to Predicate Device:

The proposed Precision QID Blood Glucose Test Strip has technological characteristics equivalent to those of the predicate Precision QID Blood Glucose Test Strip (K945887). The proposed Precision QID Test Strip is identical in form, function, material composition, manufacturing process, and equivalent in intended use to the predicate Precision QID Test Strip. The only difference between the proposed device and the predicate device involves label changes to the Precision QID Test Strip Insert Sheet and User's Manual. The proposed labeling expands the intended use and would allow healthcare professionals to use arterial whole blood samples. An additional predicate device, the Accu-Chek Advantage Test Strip (K951887), also allows healthcare professionals to use arterial whole blood samples and has the same intended use as the proposed Precision QID Test Strip in that it is intended for use by professionals and people with diabetes for the quantitative determination of glucose in whole blood.

Performance Studies:

Clinical testing using arterial whole blood was performed at a university medical center by comparison of patient results obtained with the Precision QID Blood Glucose Testing System to results obtained with both a whole blood and a plasma hexokinase reference method. Results for both reference methods are summarized below. In addition, results obtained with the predicate Precision QID Blood Glucose Test Strip using capillary whole blood as compared to a whole blood reference method are included.

Sample Type Used on Precision QID Test Strip	Precision QID Test Strip Results		
	Arterial Whole Blood*		Capillary Whole Blood**
Sample Type Used on Reference Method	Arterial Whole Blood	Arterial Plasma	Capillary Whole Blood
Correlation Coefficient (r)	0.961	0.967	0.984
Slope (m)	1.005	0.971	0.938
Y-intercept, mg/dL	-6.2	0.7	10.6
N	320	306	311
* Results are from pooled data of all test strip lots.			
** Results reported in 510(k) submission #K945887 and used for accuracy performance data in label copy.			

Conclusion:

Results of clinical testing demonstrate that the performance of the Precision QID Blood Glucose Test Strip using arterial whole blood is acceptable and comparable to the performance of the predicate Precision QID Blood Glucose Test Strip using capillary whole blood and that the Precision QID Blood Glucose Testing System is suitable for its intended use.