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510(k) Summary

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Device Name: ExacTech RSG Blood Glucose Testing System

Common Name: Blood Glucose Test System

Classification: "Glucose Test System" - Class II per CFR 862.1345

Predicate Devices: ExacTech Blood Glucose Testing System - K863468

Description: The ExacTech RSG Blood Glucose Testing System utilizes amperometric biosensor technology to quantitatively measure glucose in whole blood and control solutions. After inserting a test strip into the sensor, a drop of whole blood or control solution is applied to the target area of the test strip and the sensor button is pressed. 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 ExacTech RSG 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 30 seconds.

Intended Use: The ExacTech RSG Blood Glucose Testing System is intended for in vitro diagnostic use (i.e., for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The product is designed for home or professional use.

Comparison to Predicate Device: The ExacTech RSG Blood Glucose Testing System has technological characteristics equivalent to those of the predicate ExacTech Blood Glucose Testing System.

The hardware for the ExacTech RSG Sensor has been revised compared to the predicate ExacTech Sensor to improve user features such as ease of test strip insertion, ease of test initiation and display readability. The software for the ExacTech RSG Sensor has been revised compared to the predicate ExacTech software to include pre-programmed universal calibration information eliminating the need for a calibration procedure.

The only design difference between the new ExacTech RSG test strips and the predicate ExacTech test strips is the method of calibration. ExacTech RSG test strips do not require a user calibration procedure because the sensor is pre-programmed with universal calibration information specific to ExacTech RSG test strips.

Performance Studies: Comparative nonclinical testing of the ExacTech RSG Blood Glucose Testing System and the standard ExacTech Blood Glucose Testing System included linearity and dynamic range testing. The performance of the ExacTech RSG System was determined to be comparable to the performance of the standard ExacTech System.

Comparative clinical testing of the ExacTech RSG Blood Glucose Testing System and the standard ExacTech Blood Glucose Testing System was performed at three sites and included a clinic, physician's office, and clinical research center. A total of 178 subjects (34% male, 66% female) ranging in age from 9 to 88 years participated in the study. The majority of participants were either White or Hispanic. A diversity of both education and occupation was observed at all sites. Two of the sites had a higher percentage of subjects with NIDDM and one site had a higher percentage of subjects with IDDM.

To evaluate accuracy, capillary whole blood was collected from each subject and tested by a trained operator on both the new ExacTech RSG and standard ExacTech Systems, as well as a YSI Analyzer. Results for the three sites are summarized below and indicate that the accuracy of the ExacTech RSG System is comparable to the accuracy of the standard ExacTech System.

	ExacTech RSG System	Standard ExacTech System
Correlation Coefficient (r)	0.979	0.983
Slope (m), mg/dL	0.971	0.925
Y-intercept, mg/dL	2.2	4.7
N	288	170

To evaluate precision, venous whole blood was tested twenty times on both the new ExacTech RSG and standard ExacTech Systems. Results obtained at one of the sites are summarized below and indicate that the precision of the ExacTech RSG System is comparable to the precision of the standard ExacTech System.

ExacTech RSG System			Standard ExacTech System		
Mean, mg/dL	SD, mg/dL	CV, %	Mean, mg/dL	SD, mg/dL	CV, %
59.1	3.03	5.1	53.1	3.77	7.1
89.2	3.59	4.0	87.9	5.07	5.8
175.6	7.37	4.2	143.8	9.77	6.8
297.5	8.57	2.9	268.0	9.36	3.5

Conclusion: Results of comparative nonclinical and clinical testing demonstrate that the performance of the ExacTech RSG Blood Glucose Testing System is comparable to the performance of the standard ExacTech Blood Glucose Testing System and suitable for its intended use.