

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k131366

B. Purpose for Submission:

Modification of a previously cleared blood glucose monitoring system with insulin bolus calculator (k111353) to remove Bluetooth wireless connectivity to an insulin pump.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, amperometric assay, glucose dehydrogenase (mutant GDH-PQQ)

E. Applicant:

Roche Diagnostics Corporation

F. Proprietary and Established Names:

ACCU-CHEK Aviva Expert Blood Glucose Monitoring System

G. Regulatory Information:

Regulation	Name	Class	Product Code	Panel
21 § 862.1345	Glucose dehydrogenase, glucose test system	II	LFR	(75) Chemistry
21 § 868.1890	Calculator, drug dose	II	NDC	General and Plastic Surgery

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The ACCU-CHEK Aviva Expert System is indicated as an aid in the treatment of insulin-requiring diabetes. The ACCU-CHEK Aviva Expert System consists of the ACCU-CHEK Aviva Expert Meter, ACCU-CHEK Aviva Plus test strips, ACCU-CHEK Aviva control solutions, and ACCU-CHEK Bolus Advisor. The ACCU-CHEK Aviva Expert System is intended to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and are under the supervision of healthcare professionals experienced in managing insulin treated patients.

The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used by a single person and should not be shared. The ACCU-CHEK Aviva Expert blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Expert blood glucose monitoring system. The ACCU-CHEK Aviva Expert System is intended for prescription use only.

The ACCU-CHEK Aviva Expert meter is also indicated for the calculation of an insulin dose or carbohydrate intake based on user-entered data. The ACCU-CHEK Bolus Advisor, as a component of the ACCU-Chek Aviva Expert meter, is intended for use in providing insulin dose recommendations in response to blood glucose, health events, and carbohydrate input. The ACCUCHEK Bolus Advisor is intended to provide direction for insulin adjustment within the scope of a preplanned treatment program from a healthcare professional. Before its use, a physician or healthcare professional must prescribe the ACCU-CHEK Aviva Expert System and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the ACCU-CHEK Bolus Advisor. Once programmed, a patient must consult with his/her physician or healthcare professional before making any changes to these ACCU-CHEK Bolus Advisor settings.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- Capillary fingerstick blood only
- Not for testing on neonates
- Do not use for diagnosis or screening of diabetes mellitus
- Inaccurate results may occur in severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- Not to be used for patients who are critically ill
- For single-patient use only
- Not to be used with patients taking Neutral Protamine Hagedorn (NPH) or any other intermediate-acting insulin.
- For prescription use only
- Patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters should be provided by a physician or healthcare professional.
- Consultation with a physician or healthcare professional should occur before making any changes to the ACCU-CHEK Bolus Advisor settings.

4. Special instrument requirements:
ACCU-CHEK Aviva Expert Meter

I. Device Description:

The ACCU-CHEK Aviva Expert Blood Glucose Monitoring System consists of the following:

- ACCU-CHEK Aviva Expert meter
- ACCU-CHEK Bolus Advisor (a component of the Aviva Expert meter)
- ACCU-CHEK Aviva Plus test strips (k101299)
- ACCU-CHEK Aviva control solutions (k043474)
- ACCU-CHEK FastClix lancing device

The ACCU-CHEK Aviva Expert system is a blood glucose monitoring system that makes use of the ACCU-CHEK Aviva Plus test strips (cleared under k101299; mutant GDH-PQQ) and the ACCU-CHEK Aviva 2 level control solutions (cleared under k043474). The ACCU-CHEK Aviva Expert meter is nearly identical to that of the ACCU-CHEK Aviva Combo meter (cleared under k111353); however, the ACCU-CHEK Aviva Expert meter does not have Bluetooth capabilities to connect wirelessly to an insulin pump.

The ACCU-CHEK Aviva Expert system provides the user with the ability to measure capillary blood glucose levels when a sample of capillary blood is applied to the test strip. The meter also provides an optional insulin bolus calculator (the ACCU-CHEK Bolus Advisor) designed for use by individuals with diabetes who require multiple daily insulin injection (MDI) therapy. The insulin bolus calculation function is optional in that a user can simply obtain a blood glucose value through capillary blood testing and does not need to use the insulin bolus calculator portion of the system if it is not desired. The insulin bolus calculator algorithm is identical to the bolus calculator algorithm that was cleared during the Aviva Combo 510(k) submission (k111353). In order to calculate the appropriate bolus of insulin, the ACCU-CHEK Bolus Advisor takes into account the measured blood glucose, the target blood glucose, the carbohydrate intake, the insulin-to-carbohydrate ratio, the insulin sensitivity, health events (such as exercise), the time of day, and the active insulin. Before using the ACCU-CHEK Aviva Expert system, a physician or healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ACCU-CHEK Aviva Combo Blood Glucose Meter
2. Predicate 510(k) number(s):
k111353
3. Comparison with predicate:

Similarities		
Item	Device- ACCU-CHEK Aviva Expert System (k131366)	Predicate- ACCU-CHEK Aviva Combo Blood Glucose System (k111353)
Indications for Use	Same	Quantitative measurement of glucose (sugar) in capillary blood from the finger tip, indicated for diabetes management by calculating an insulin dose or carbohydrate intake.
Insulin bolus calculator	Same	Insulin bolus calculator for insulin dosing calculations.
Test Strip	Same	Aviva Plus Test Strip
Test Principle	Same	Amperometric Detection
Enzyme	Same	Mutant Q-GDH PQQ
Hematocrit Range	Same	10 to 65%
Maximum Altitude	Same	10,000 feet
Measuring Range	Same	20 – 600 mg/dL
Sample Volume	Same	0.6 mL
Test Time	Same	5 seconds
Operating Temperature and Relative Humidity	Same	14 to 38°C (57 to 100°F), 10-80% r.h.
Coding	Same	Code key insertion; lot-specific code key provided with each box of Aviva Plus test strips
Closed and Open Test Strip Shelf Life Stability	Same	18 months
Control Solutions	Same	Aqueous, 2 levels, uses ACCU-CHEK Aviva Control Solutions

Differences		
Item	Device- ACCU-CHEK Aviva Expert System (k131366)	Predicate- ACCU-CHEK Aviva Combo Blood Glucose System (k111353)
RF Wireless Capability	No Bluetooth capability	Yes; Bluetooth wireless communication with ACCU-CHEK Spirit Combo insulin infusion pumps.
Measurement Units of Insulin Bolus Result	0.5 units (appropriate for syringe/pen administration)	0.1 units (appropriate for pump administration of

Differences		
Item	Device- ACCU-CHEK Aviva Expert System (k131366)	Predicate- ACCU-CHEK Aviva Combo Blood Glucose System (k111353)
Calculations	of insulin)	insulin)
Basal Insulin	Diary feature for tracking basal insulin	Basal insulin is controlled via pump
User Group	Diabetes patients treated with multiple daily insulin injection (MDI) therapy	Diabetes patients treated with insulin pump therapy or multiple daily insulin injection (MDI) therapy

K. Standard/Guidance Document Referenced (if applicable):

ISO 14971: 2007, Medical devices – Application of risk management to medical devices
 FDA Guidance: 2005: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

L. Test Principle:

When an ACCU-CHEK Aviva Plus test strip is inserted into the ACCU-CHEK Aviva Expert meter, a small alternating current (AC) is applied until the application of blood causes a spike in the conductivity to be observed at the measurement and sample sufficiency electrodes – both are used to assure an adequate sample has been applied. The instrument then applies a series of AC voltages at four frequencies and reads the AC responses. These carry information about the sample type and environmental temperature; they also allow the system to perform various internal quality checks. After the AC measures are completed, a small (DC) voltage is applied and current is observed which is proportionate to the glucose. The AC and DC information are then combined to provide a hematocrit and temperature compensated glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

As established in k111353

b. *Linearity/assay reportable range:*

As established in k111353

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability is to NIST SRM 917 and was established under k101299.

ACCU-CHEK Aviva Plus test strip stability was evaluated under k101299. Closed and open vial test strip stability is 18 months when stored at 36-86° F (2-30°C).

ACCUCHEK Aviva control solutions stability and value assignment was evaluated under k043474. Closed vial stability at 36-90°F is 24 months from the date of manufacture. Open vial stability is 3 months from the date of opening.

d. Detection limit:

As established in k111353. The reportable range is 20-600 mg/dL.

e. Analytical specificity:

As established in k111353.

The sponsor has the following limitations in their labeling:

- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

As established in k111353.

b. Matrix comparison:

Not applicable. The device is for fingerstick capillary blood only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The sponsor included the following expected values in the labeling:

The fasting glucose level for a non-diabetic adult is below 100 mg/dL.^{1,2}

Two hours after meals the normal blood glucose level for a non-diabetic is less than 140 mg/dL.¹

¹American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement). Diabetes Care 34 (Supp. 1) S66, 2011.

²Tietz Fundamentals of Clinical Chemistry, 6th Edition, Edited by Burtis CA and Ashwood ED, W. B. Saunders Co., Philadelphia, PA, 2008, p. 849.

N. Instrument Name:

ACCU-CHECK Aviva Expert Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings. Before using the ACCU-CHEK Bolus Calculator on the ACCU-CHEK Aviva Expert system, a physician or healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters. Labeling is provided for the Bolus Calculator functions.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes X or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No X

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No _____

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

The glucose test is intended to be used with capillary whole blood from the finger. The sample is applied directly to the test strip and testing is performed immediately. Sample storage is not required.

5. Calibration:

Each lot of test strips contains a code key specific to the lot and the key must be inserted into the meter prior to using a new lot of strips.

6. Quality Control:

Two levels of aqueous glucose control solutions are available with this system (Level 1, Level 2) but must be purchased separately. The meter automatically recognizes control materials as separate from patient samples and identifies them as controls on the display screen. Control results are not included in patient glucose averaging. Recommendations on when to test the control materials and troubleshooting steps if the controls are outside of specifications are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

1. Hematocrit study: As established in k111353 the claimed hematocrit range is 10-65%.
2. Altitude study: As established in k111353 the claimed altitude is 10,000 ft.
3. Infection Control Study: As established in k111353. The ACCU-CHECK Aviva Expert Blood Glucose Monitoring System is for single patient use only and validation testing supported the use of Super Sani-Cloth (EPA reg. no. 9480-4) for 260 cleaning and disinfection cycles to simulate 5 years of single-patient meter use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures
4. Environmental testing for temperature and relative humidity: As established in k111353. Operating temperature and humidity ranges are from 57-100°F (14-38°C), 10-80% RH.
5. Sample volume requirements: As established in k111353 the minimum sample volume is 6 mL.
6. EMC and electrical safety: As established in k111353.
7. Usability study: As established in k111353.
8. Readability study: As established in k111353.
9. Customer support is available 24 hrs./day, 7 days per week by calling 1-800-688-4578.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.