June 12, 2026

Roche Diagnostics
Teresa Carrow
Senior Regulatory Affairs Manager
9115 Hague Road
Indianapolis, Indiana 46250

Re: K252323
Trade/Device Name: cobas® pulse blood glucose monitoring system
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: PZI
Dated: March 13, 2026
Received: March 16, 2026

Dear Teresa Carrow:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO
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Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252323

Device Name
cobas® pulse blood glucose monitoring system

Indications for Use *(Describe)*
The cobas® pulse blood glucose monitoring system consists of the cobas® pulse instrument and the cobas® GLU test strips.
This system is intended for in vitro diagnostic, point of care, multiple-patient use within professional healthcare settings, including patients receiving intensive medical intervention/therapy.
The cobas® GLU test strips provide an in vitro diagnostic test that quantitatively measures glucose in venous whole blood, arterial whole blood, neonate arterial whole blood, or neonate heel stick whole blood samples, on the cobas® pulse system.
For neonate heel stick, the system should only be used with single-use, auto-disabling lancing devices.
This system is not intended for use with capillary finger stick, neonate cord blood specimens or neonate venous specimens.
This system is not intended for screening or diagnosis of diabetes, but is indicated for use in determining dysglycemia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

cobas® pulse

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

In accordance with 21 CFR 807.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification 510(k).

Document #	K252323 & CW250013
Type of 510(k)	Dual Submission 510(k) and CLIA Waiver
Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Teresa Carrow Phone: (317) 521-2963 Email: teresa.carrow@roche.com
Date Prepared	June 5, 2026
Proprietary Name	**cobas®** pulse blood glucose monitoring system
Common Name	**cobas®** pulse blood glucose monitoring system
Classification Name	Prescription Use Blood Glucose Meter for Near-patient Testing
Product Codes, Regulation Numbers	PZI (Class 2), Prescription Use Blood Glucose Meter for Near-patient Testing 21 CFR 862.1345 – Glucose test system
Predicate Devices	StatStrip Glucose Hospital Meter System, K181043
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126

1. DEVICE DESCRIPTION

The **cobas®** pulse blood glucose monitoring system consists of a hand-held, battery powered **cobas** pulse instrument, single use **cobas** GLU test strips (sold separately), instrument charging station, quick start guide and user guide for CLIA waived users as well as **cobas** GLU test strip insert and user assistance guide for non-CLIA waived users. The **cobas** GLU QC kit control solutions (Levels 1 and 2) and **cobas** GLU Linearity Kit (6 levels) are sold separately.
The test strips contain FAD-dependent glucose dehydrogenase enzyme that oxidizes glucose to generate a current proportional to the concentration of glucose present in the blood sample. The meter detects and converts the electrical current into a blood glucose concentration that corresponds to the plasma fraction of the applied whole blood sample

2. INDICATIONS FOR USE

The **cobas®** pulse blood glucose monitoring system consists of the **cobas®** pulse instrument and the **cobas®** GLU test strips.

This system is intended for in vitro diagnostic, point of care, multiple-patient use within professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The **cobas®** GLU test strips provide an in vitro diagnostic test that quantitatively measures glucose in venous whole blood, arterial whole blood, neonate arterial whole blood, or neonate heel stick whole blood samples, on the **cobas®** pulse system.

For neonate heel sick, the system should only be used with single-use, auto-disabling lancing devices.

This system is not intended for use with capillary finger stick, neonate cord blood specimens or neonate venous specimens.

This system is not intended for screening or diagnosis of diabetes, but is indicated for use in determining dysglycemia.

3. TECHNOLOGICAL CHARACTERISTICS

The **cobas** pulse blood glucose monitoring system is substantially equivalent to the StatStrip Glucose Hospital Meter System cleared under K181043.

The laboratory comparison method for this submission is the **cobas** 6000 system (K060373) using the glucose plasma hexokinase reagent (K191899).

The **cobas** pulse blood glucose monitoring system has the same scientific technology as the device cleared under K220272 / CW220002. No changes have been made to the meter hardware, the test strips, the controls, or the linearity solutions. The only change is to the software and the labeling of the device to allow the product to be used on venous whole blood samples in patients throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.

The following Table 1 compares the **cobas** pulse with its predicate device, StatStrip Glucose Hospital Meter System (K181043).

Table 1: Technical Characteristics Comparison Table between cobas pulse and StatStrip

Feature	Candidate Device: cobas pulse	Predicate Device: StatStrip
Intended Use	The **cobas**® pulse blood glucose monitoring system consists of the **cobas**® pulse instrument and the **cobas**® GLU test strips. This system is intended for in vitro diagnostic, point of care, multiple-patient use within professional healthcare settings, including patients receiving intensive medical intervention/therapy. The **cobas**® GLU test strips provide an in vitro diagnostic test that quantitatively measures glucose in venous whole blood, arterial whole blood, neonate arterial whole blood, or neonate heel stick whole blood samples, on the **cobas**® pulse system. For neonate heel stick, the system should only be used with single-use, auto-disabling lancing devices. This system is not intended for use with capillary finger stick or neonate cord blood specimens or neonate venous specimens. This system is not for screening or diagnosis of diabetes, but is indicated for use in determining dysglycemia.	The StatStrip Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens throughout all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy. The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick. It is not intended for use with neonate cord blood specimens. It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
Test platform	Same	Single use test strip
Enzyme	FAD-GDH	Glucose Oxidase
Test Principle	Amperometric Detection	Enzyme, Amperometric Detection
Sample Volume	0.6 µL	1.2 µL
Measurement Range	Same	10-600 mg/dL
Hematocrit Range	5% - 70%	20-70%

Feature	Candidate Device: cobas pulse	Predicate Device: StatStrip
Operating Temperature Range	12-40°C / 54-104°F	15-40°C / 59-104°F
Operating Relative Humidity Range	Same	10% to 90% non-condensing
Maximum Altitude	4300 meters / 14,107 feet	4500 meters / 15,000 feet
Test Strip Storage Temperature	4-30°C / 36-86°F Do not freeze. Store away from extreme temperatures and moisture levels.	1-30°C / 34-86°F
Test Strip Shelf Life	Same	24 months
Underdose Detection	Yes	none
Control Solutions	Aqueous, 2 Levels	Liquid, 3 Levels
Linearity Kit	Aqueous, 6 Levels	Liquid, 5 Levels
Battery	3.6 V rechargeable battery pack (lithium technology)	3.7 V rechargeable Lithium ion battery
Transmission of Retrospective Data to External Devices	Same	Wirelessly to WLAN through RF communication
Meter Physical Appearance	Length x Width x Height 200 mm x 77 mm x 30 mm 7.87 in x 3.03 in x 1.18 in	Length x Width x Height 147 mm x 79 mm x 30 mm 5.8 in x 3.1 in x 1.18 in
Labeling	For multi-patient use. Test strip package insert provides accuracy data on venous, arterial, neonate arterial and neonate heel stick sample types.	For multi-patient use. Test strip package insert provides accuracy data on capillary, venous, arterial, neonate arterial and neonatal sample types.
Calibration method	The system is factory calibrated. No customer calibration needed.	Automatic, no calibration code
Operating System Software	Android	Touch screen graphical user interface

4. NON-CLINICAL PERFORMANCE EVALUATION

The **cobas** pulse blood glucose monitoring system was updated to change the software of the device to support the additional venous sample type. This software change has not impacted the device performance since the previous clearance on K220272/CW220002. No technological, material, performance, or design changes to the **cobas** pulse blood glucose monitoring system have been implemented since its clearance on K220272/CW220002. The following performance

data was provided as part of that clearance in support of the substantial equivalence determination.

- Precision (Repeatability and Intermediate Precision)
- Linearity (10-600 mg/dL)
- Endogenous and Exogenous Interferences
- Flex Studies
- Electromagnetic Interference and Electrical Safety
- Stability
- Cleaning and Disinfecting

5. CLINICAL PERFORMANCE EVALUATION

5.1. Method Comparison versus Reference System

The glucose results of the **cobas** pulse system were compared to those from a plasma-based hexokinase (HK) reference method (GLUC3) on the Roche **cobas** 6000 system.

The performance of the cobas pulse glucose monitoring system was assessed in professional healthcare settings using lithium heparin venous samples from 643 subjects, both critically ill and non-critically ill with and without diabetes (adult and pediatric), within professional use Point of Care locations to best reflect the intended use environment of the instrument. These included outpatient clinics, urgent care centers, and hospital departments, such as general wards, critical care units [i.e., pediatric ICU, medical ICU, surgical ICU], operating rooms, and emergency departments. There were a total of 7 external sites and 28 self-trained operators performing this testing.

Samples from patients 1 year to over 81 years of age were analyzed using a total of 3 different test strip lots throughout the study. There were 282 (44%) male and 361 female (56%) participants. The glucose levels of the patient samples were (according to the comparator method; the **cobas** 6000 system) 26.1 to 482.6 mg/dL. In addition to glucose levels, patient conditions, medication information, sodium, and hematocrit levels were collected during the study. The study included subjects with 665 unique patient conditions corresponding to 26 system organ classes. Participants had received a total of 616 medications representing 73 parent drug classes.

5.1.1. Method Comparison versus Reference System

Table 5: Accuracy Comparison between Plasma-HK on the cobas 6000 system and the cobas pulse system: Glucose concentrations <75 mg/dL

Sample Type	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
Venous vs. Venous	93/110 (84.5%)	109/110 (99.1%)	110/110 (100.0%)	110/110 (100.0%)	0/110 (0.0%)

Table 6: Accuracy Comparison between Plasma-HK on the cobas 6000 system and the cobas pulse system: Glucose concentrations ≥75 mg/dL

Sample Type	Within ±5%	Within ±10%	Within ±12%	Within ±15%	Within ±20%	Exceeds ±20%
Venous vs. Venous	444/533 (83.3%)	524/533 (98.3%)	529/533 (99.2%)	533/533 (100.0%)	533/533 (100.0%)	0/533 (0.0%)

Table 7: Accuracy Comparison between Plasma-HK on the cobas 6000 system and the cobas pulse system: All glucose concentrations with breakpoint of 75 mg/dL

Sample Type	Within (±5 mg/dL /5%) rate (%)	Within (±10 mg/dL /10%) rate (%)	Within (±12 mg/dL /12%) rate (%)	Within (±15 mg/dL /15%) rate (%)	Within (±20 mg/dL /20%) rate (%)	Exceeds (±20 mg/dL /20%) rate (%)
Venous vs. Venous	537/643 (83.5%)	633/643 (98.4%)	639/643 (99.4%)	643/643 (100.0%)	643/643 (100.0%)	0/643 (0.0%)

6. CLIA WAIVER

Data collected in this study has been evaluated to demonstrate accuracy based on the acceptance criteria described in the FDA Guidance Document: Recommendations for Clinical Laboratory Improvement Amendments (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostics Devices, February 2020.

6.1. Demonstrating Simple

The **cobas** pulse blood glucose monitoring system:

- Consists of the fully automated **cobas** pulse instrument and **cobas** GLU test strips.

- Uses direct, unprocessed whole blood samples and requires no specimen manipulation before performing the test.
- Reagents are secured within the test strip.
- Instrument graphically shows a step-by-step procedure on how to perform a glucose test. Once the test strip is inserted into the meter, the sample is applied directly to the test strip and the test result is displayed. There are no further procedural steps.
- Requires no operator intervention during the analysis steps.
- Requires no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes. Error messages are unambiguous, and include easy-to-interpret solutions.
- Requires no electronic or mechanical maintenance. Maintenance consists of general external cleaning and disinfection of the instrument.
- Includes a quick reference guide (QRG) and user guide (UG) containing instructions for the CLIA waived user.

6.2. Demonstrating Insignificant Risk of an Erroneous Result – Failure Alerts and Fail-safe Mechanisms

1. Risk Assessment

This submission shows CLIA Waiver through the Dual 510(k) / CLIA Waiver Submission process. A comprehensive risk analysis was conducted for the **cobas** pulse blood glucose monitoring system to assess the risks of providing incorrect patient results, the safety risks to the patient or operator associated with the operation of the system, and to demonstrate that the system is robust to known sources of error. All risks of harm to the patient or operator were mitigated to an acceptable level, and the system was demonstrated to be robust to known sources of error.

2. Fail Safe and Failure Alert Mechanisms

The system will provide an error message, or a lockout function will occur and will not allow output of quantitative test results for the following conditions:

- If the battery is low, a 'battery low icon' is displayed.
- Error messages are displayed when a test strip is incorrectly inserted or previously used -- the user is instructed to rerun the test with a new test strip.
- Error messages are displayed when the specimen is incorrectly drawn into the test strip due to insufficient volume or incorrect sample application.
- 'HI' is displayed when the glucose result is greater than 600 mg/dL.
- 'LO' is displayed when the glucose result is less than 10 mg/dL.

External control material is recommended to demonstrate that the **cobas** pulse instrument and test strips are working properly. The labeling states that the user should perform quality control testing only with the **cobas** GLU QC kit.

Number of **cobas** pulse GLU QC kit control solutions: 2 levels (Level 1, Level 2).

Directions for use are clearly stated in the labeling (Quick Reference Guide, User Guide, and **cobas** GLU test strip insert).

It is recommended that two different levels of **cobas** GLU QC kit control solutions be run every 24 hours of testing, prior to testing of patient specimens, and during the following circumstances:

- the first time before using the instrument for patient testing,
- the first time the instrument is used by the operator,
- at shorter QC intervals if established by the workplace,

- when a new test strip container is opened,
- if there is a doubt about patient's glucose result,
- to test correct performance of the system,
- if the instrument was dropped, and
- when other problems are suspected or identified (e.g., instrument outside of environmental conditions).

Storage and stability are stated in labeling. The user should follow the manufacturer's instructions for storage and stability.

3. Flex Studies

The same flex studies information as included in K220272 and CW220002 applies.

6.3. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy

The same accuracy information as listed in Section 5 applies.

6.4. Labeling for Waived Devices

- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.
- The User Guide and Quick Reference Guide are written at no higher than a 7th grade reading level.
- The User Guide, Quick Reference Guide, and **cobas** GLU test strip package insert identify the test as CLIA waived.
- The User Guide, Quick Reference Guide, and **cobas** GLU test strip package insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.

- The User Guide, Quick Reference Guide, and **cobas** GLU test strip package insert contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e)(1).
- The User Guide and Quick Reference Guide provide instructions for conducting quality control procedures.

7. ADDITIONAL INFORMATION

Other materials required but not provided:

- Control: **cobas** GLU QC kit (Level 1 and Level 2), Class I exempt

Other optional materials not provided:

- Linearity kit: **cobas** GLU linearity kit (6 levels), Class I exempt

8. CONCLUSIONS

The results obtained from the nonclinical (presented in K220272 and CW220002) and clinical evaluations confirmed that the **cobas** pulse blood glucose monitoring system is safe and effective when used with venous whole blood in the multiple professional health care environments and patient populations outlined in its intended use.

In the sample type measured, the **cobas** pulse blood glucose monitoring system displayed substantial equivalence to the legally marketed predicate device, StatStrip Glucose Hospital Meter System (K181043).

Also, these results demonstrate Simple and Insignificant Risk of an Erroneous Result when used by untrained operators in the intended use setting.

The submitted information in this Dual 510(k) and CLIA Waiver submission application is complete and supports both a substantial equivalence and CLIA waiver approval decision.