April 2, 2026

Roche Diagnostics
Elina Voronovsky
Senior Regulatory Affairs Manager
9115 Hague Rd.
Indianapolis, Indiana 46250

Re: K260026
Trade/Device Name: Tina-quant Cardiac high sensitivity CRP III
Regulation Number: 21 CFR 866.5270
Regulation Name: C-Reactive Protein Immunological Test System
Regulatory Class: Class II
Product Code: NQD
Dated: December 19, 2025
Received: January 5, 2026

Dear Elina Voronovsky:

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 -S

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)*
K260026

Device Name
Tina-quant Cardiac high sensitivity CRP III

Indications for Use *(Describe)*
The Tina-quant Cardiac high sensitivity CRP III application is an in vitro test for the quantitative determination of C reactive protein (CRP) in human serum and plasma on cobas c systems. Cardiac high sensitive measurement of CRP may be used as an aid in the assessment of the risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation methods of acute coronary syndromes, it may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Tina-quant Cardiac high sensitivity CRP III
K260026 – 510(k) Summary

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

Submitter Name	Roche Diagnostics
Address	9115 Hague Road P.O. Box 50416 Indianapolis, IN 46250-0457
Contact	Elina Voronovsky Phone: (317) 478-3317 Email: elina.voronovsky.ev1@roche.com
Date Prepared	March 31, 2026
Proprietary Name	Tina-quant Cardiac high sensitivity CRP III
Common Name	Tina-quant Cardiac high sensitivity CRP III
Classification Name	C-reactive protein immunological test system
Product Codes, Regulation Numbers	NQD, 866.5270
Predicate Devices	C-Reactive Protein (Latex) High Sensitive test system (K053603)
Establishment Registration	Roche Diagnostics GmbH Mannheim, Germany: 9610126 Roche Diagnostics GmbH Penzberg, Germany: 9610529 Roche Diagnostics Indianapolis, IN United States: 1823260

1. DEVICE DESCRIPTION

The Tina-quant Cardiac high sensitivity CRP III application is an in vitro test for the quantitative determination of C-reactive protein (CRP) in human serum and plasma on **cobas** c systems. Cardiac high sensitive measurement of CRP may be used as an aid in the assessment of the risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation methods of acute coronary syndromes, it may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.

The Tina-quant Cardiac high sensitivity CRP III assay is a particle enhanced immunoturbidimetric assay.

Reagents - working solutions

R1 TRIS A) buffer with bovine serum albumin, pH 7.6; preservative

R3 Latex particles (0.31 % w/w) coated with anti-CRP (mouse) in glycine buffer; immunoglobulins (mouse, 0.0075 % w/w), pH 8.0; preservative

A) TRIS = Tris(hydroxymethyl)-aminomethane

2. INDICATIONS FOR USE

The Tina-quant Cardiac high sensitivity CRP III application is an in vitro test for the quantitative determination of C-reactive protein (CRP) in human serum and plasma on **cobas** c systems. Cardiac high sensitive measurement of CRP may be used as an aid in the assessment of the risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation methods of acute coronary syndromes, it may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.

3. TECHNOLOGICAL CHARACTERISTICS

The following table compares the Tina-quant Cardiac high sensitivity CRP III assay on **cobas** c 503 with its predicate device, C-Reactive Protein (Latex) High Sensitive test system (K053603).

Table 1: Tina-quant Cardiac high sensitivity CRP III Technical Characteristics

	Candidate Device: Tina-quant Cardiac high sensitivity CRP III (HSCRP)	**Predicate Device: C-Reactive Protein (Latex) High Sensitive test system (K053603)**
Intended Use / Indications for Use	The Tina-quant Cardiac high sensitivity CRP III application is an in vitro test for the quantitative determination of C-reactive protein (CRP) in human serum and plasma on **cobas** c systems. Cardiac high sensitive measurement of CRP may be used as an aid in the assessment of the risk for future cardiovascular disease. When used in conjunction with traditional clinical laboratory evaluation methods of acute coronary syndromes, it may be useful as an independent marker of prognosis for recurrent events in patients with stable coronary disease or acute coronary syndrome.	The CRP (Latex) High Sensitive Immunoturbidimetric assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on Roche automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Highly sensitive measurement of CRP may also be used as an aid in the assessment of the risk of future coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may also be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.
Assay Method	Same	Particle-enhanced immunoturbidimetric assay
Detection Method	Same	Turbidimetric

	Candidate Device: Tina-quant Cardiac high sensitivity CRP III (HSCRP)	**Predicate Device: C-Reactive Protein (Latex) High Sensitive test system (K053603)**
Instrument Platform	**cobas** c systems	COBAS INTEGRA
Sample Type/ Matrix	Same	Human serum and plasma
Calibrator	Same	S1: H_2O S2-S6: C.f.a.s. Proteins
Calibration Method	Same	Non-linear
Calibration Interval	Same	Calibration frequency Full calibration - after reagent lot change - as required following quality control procedures
Controls	CRP T Control N PreciControl ClinChem Multi 1	CRP T Control N Precinorm Protein
Traceability/ Standardization	This method has been standardized against the certified reference material in human serum of the IRMM (Institute for Reference Materials and Measurements) ERM-DA474/IFCC, which is directly traceable to ERM-DA470 (formerly named CRM470).	This method has been standardized against the reference preparation of the IRMM (Institute for Reference Materials and Measurements) BCR470/CRM470 (RPPHS - Reference Preparation for Proteins in Human Serum)
Reagent Stability	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer (opened and refrigerated): 24 weeks	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer (opened and refrigerated): 12 weeks
Measuring Range	0.150-10.0 mg/L	0-20 mg/L
Lower Limits of Measurement	LoB = 0.100 mg/L LoD = 0.150 mg/L LoQ = 0.150 mg/L	Limit of Detection = 0.1 mg/L

	Candidate Device: Tina-quant Cardiac high sensitivity CRP III (HSCRP)	Predicate Device: C-Reactive Protein (Latex) High Sensitive test system (K053603)
Method Comparison	Sample size (n) = 104 Passing/Bablok y = 1.068x – 0.0302 mg/L τ = 0.982 r = 0.999 The sample concentrations were between 0.395 and 8.59 mg/L.	

4. NON-CLINICAL PERFORMANCE EVALUATION

Performance characteristics were evaluated with Tina-quant Cardiac high sensitivity CRP III on **cobas** c 503 and are briefly summarized below.

All acceptance criteria were met.

4.1. Precision

4.1.1. Repeatability and Intermediate Precision

Precision experiments were performed in accordance with CLSI guideline EP05-A3. Two aliquots per run, two runs per day for ≥ 21 days were performed on the same **cobas** c 503 analyzer using 3 lots of reagent. Repeatability (within run precision) and intermediate precision (within lab precision) were calculated. All acceptance criteria were met.

Repeatability			
Specimen	**Mean (mg/L)**	**SD (mg/L)**	**CV (%)**
CRPTN	4.14	0.0158	0.4
PCCC1	6.40	0.0222	0.3
Serum 1	0.429	0.00795	1.9
Serum 2	1.09	0.0184	1.7
Serum 3	2.93	0.0159	0.5
Serum 4	6.46	0.0340	0.5
Serum 5	9.86	0.0432	0.4

Repeatability			
Intermediate Precision			
Specimen	**Mean (mg/L)**	**SD (mg/L)**	**CV (%)**
CRPTN	4.14	0.0216	0.5
PCCC1	6.44	0.0643	1.0
Serum 1	0.429	0.00826	1.9
Serum 2	1.09	0.0221	2.0
Serum 3	2.93	0.0225	0.8
Serum 4	6.46	0.0517	0.8
Serum 5	9.86	0.0636	0.6

4.2. Analytical Sensitivity

4.2.1. Limit of Blank (LoB)

For determination of LoB, one analyte-free saline (0.9% NaCl) sample was measured with three reagent lots in 6 runs, each run with 10-fold determination, distributed over 3 days, on one **cobas** c 503 analyzer. The LoB was determined according to CLSI EP17-A2. The LoB claim in the labeling will be set to ≤ 0.100 mg/L.

4.2.2. Limit of Detection (LoD)

For determination of LoD, 5 serum samples containing low levels of CRP diluted with analyte-free saline (0.9% NaCl) were measured on three lots with 2-fold determination per run on one **cobas** c 503 analyzer. Six runs were distributed over 3 days. The LoD was determined according to CLSI EP17-A2. The LoD claim in the labeling will be set to ≤ 0.150 mg/L.

4.2.3. Limit of Quantitation (LoQ)

For determination of LoQ, 5 serum samples containing CRP were measured with three reagent lots on one **cobas** c 503. Six runs were distributed over 5 days. The Limit of Quantitation (LoQ) was determined according to CLSI EP17-A2. The LoQ claim in the labeling will be set to 0.150 mg/L.

4.3. Linearity/Assay Reportable Range

The linearity of the Tina-quant Cardiac high sensitivity CRP III assay was assessed according to CLSI EP06-A-Ed2.

A dilution series was prepared from a high sample and diluted by a CRP-low sample. The dilution series spanning the measuring range was prepared to obtain ≥ 9 levels. Samples were assayed on one **cobas** c 503 analyzer using 3 reagent lots and 4 replicates per sample. The linearity data was analyzed according to CLSI EP06-Ed2.

Linearity was confirmed for the measuring range of 0.150 – 10.0 mg/L.

4.4. High Dose Hook Effect

High-dose hook effect study was performed using the Tina-quant Cardiac high sensitivity CRP III assay and confirmed that no false result occurs up to a CRP concentration of 1000 mg/L.

4.5. Endogenous Interferences

Endogenous substances (conjugated and unconjugated bilirubin, hemolysis, lipemia (Intralipid), Immunoglobulin G (IgG), albumin, rheumatoid factor, triglycerides) were evaluated for potential interference with the Tina-quant Cardiac high sensitivity CRP III assay on the **cobas** c 503 analyzer.

All predefined acceptance criteria were met, and the proposed labeling claims for each endogenous substance can be found below:

Endogenous Substance	**Claim** **No interference up to**
Icterus	I index of 60 for conjugated bilirubin and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L).
Hemolysis	H index of 700 (approximate hemoglobin concentration: 435 µmol/L or 700 mg/dL)
Lipemia (Intralipid)	L index of 1000
Albumin	60 g/L
Immunoglobulin G	60 g/L
Rheumatoid factors	500 IU/mL
Triglycerides	500 mg/dL

4.6. Exogenous Interferences – Drugs

An exogenous interference study was conducted to evaluate commonly used pharmaceuticals and in addition, special pharmaceuticals were tested with Tina-quant Cardiac high sensitivity CRP III on the **cobas** c 503 analyzer. All acceptance criteria were met.

Drug	Concentration tested (mg/L)
Atorvastatin	0.75
Lisinopril	0.25
Metoprolol succinate	1.5
Warfarin	75
Repaglinide	1.15
Hydrochlorothiazide	1.13
Clonidine	0.0195
Apixaban	6
Ezetimibe	0.0213
Fenofibrate	45
Valsartan	11.7
Spironolactone	0.56
Clopidogrel	45
Glimepiride	1.64
Empagliflozin	10.5
Liraglutide	0.17
Amlodipine	0.075
N-Acetylcysteine	150
Acetylsalicylic acid	30
Ampicillin-Na	75
Ascorbic acid	52.5
Cefoxitin	750
Doxycyclin	18
Heparin	3300 IU/L
Levodopa	7.5
Methyldopa	22.5
Metronidazole	123
Rifampicin	48
Evolocumab	6
Icosapent ethyl	2400

Drug	Concentration tested (mg/L)
Metformin	12
Sitagliptin	60
Hydralazine	14.4
Prazosin	3
Cyclosporine	1.8
Phenylbutazone	321
Acetaminophen	156
Ibuprofen	219
Theophylline	60

4.7. Sample Matrix Comparison

The effect on quantitation of CRP values in the presence of anticoagulants with the Tina-quant Cardiac high sensitivity CRP III assay was determined on the **cobas** c 503 analyzer by comparing values obtained from samples collected in serum, Li-Heparin and K2-EDTA plasma tubes. The study was performed using 70 samples. All predefined acceptance criteria were met, supporting the labeling claim that serum, Li-Heparin, and K2-EDTA acceptable sample types.

Anticoagulant	Slope	Intercept (mg/L)	Correlation Coefficient	Concentration of Samples (mg/L)
Serum vs. Li-Heparin plasma	1.028	-0.0271	1.000	0.185 – 9.23
Serum vs. K2-EDTA plasma	1.023	-0.0288	0.999	0.185 – 9.23

4.8. Method Comparison to Predicate

A method comparison of the Tina-quant Cardiac high sensitivity CRP III (HSCRP) on the **cobas** c 503 analyzer versus the predicate device, Cardiac C-Reactive Protein (Latex) High Sensitive (CRPHS) on **cobas** c 503, was completed to support comparability to the predicate device. 104 unaltered native serum samples were tested in 1 run on 1 **cobas** c 503 analyzer, in singlet using 1 lot of reagent. The sample concentrations were between 0.395 mg/L and 8.59 mg/L. The results can be found below:

Passing/Bablok

y = 1.068x - 0.0302 mg/L

r = 0.999

4.9. Stability

The stability data supports Roche Diagnostic's claims as reported in the package labeling. Sample stability claims can be found below:

Stability in serum and Li-heparin plasma:

- 14 days at 15-25 °C
- 28 days at 2-8 °C
- 12 months at -20 °C (±5 °C)

Stability in K2 EDTA plasma:

- 2 days at 15-25 °C
- 28 days at 2-8 °C
- 12 months at -20 °C (±5 °C)

Specimens can be repeatedly frozen and thawed up to 4 times.

5. EXPECTED VALUES/REFERENCE RANGE

A statement of the CDC/AHA from 2003 recommended the following hsCRP cut-off points (tertiles) for CVD risk assessment for adults:

hsCRP level (mg/L)	**Relative risk**
< 1.0	low
1.0-3.0	average
> 3.0	high

Pearson TA, Mensah GA, Alexander RW, et al. Markers of Inflammation and Cardiovascular Disease. Application to Clinical and Public Health Practice. A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association. Circulation 2003;107:499-511.

Ridker PM. Clinical Application of C-Reactive Protein for Cardiovascular Disease Detection and Prevention. Circulation 2003;107:363-369.

6. CONCLUSIONS

The analytical performance data for Tina-quant Cardiac high sensitivity CRP III assay met the acceptance criteria and support the substantial equivalence of Tina-quant Cardiac high sensitivity CRP III assay on **cobas** c 503 analyzer to the C-Reactive Protein (Latex) High Sensitive test system.