February 27, 2026

Siemens Healthcare Diagnostics Inc.
Anthony Calabro
Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY, 10591, USA

Re: K251998
Trade/Device Name: Atellica CH Diazo Total Bilirubin (D_TBil)
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG, MQM
Dated: January 26, 2026
Received: January 26, 2026

Dear Anthony Calabro:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251998

Device Name
Atellica CH Diazo Total Bilirubin (D_TBil)

Indications for Use *(Describe)*
The Atellica CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in human serum and plasma of adults and neonates using the Atellica CH Analyzer. Measurement of total bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder block. A total bilirubin measurement in newborn infants is intended to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

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:

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510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

The assigned 510(k) Number is: K251998

1. Date Prepared

February 26, 2026

2. Applicant Information

Contact: Anthony Calabro
Regulatory Affairs Specialist

Address: Siemens Healthcare Diagnostics Inc.
P.O. Box 6101, M/S 514
Newark, DE 19714-1601

Email: anthony.calabro@siemens-healthineers.com

3. Regulatory Information

Atellica CH Diazo Total Bilirubin (D_TBil)

Trade Name: Atellica CH Diazo Total Bilirubin (D_TBil)
Common Name: Bilirubin (total or direct) test system
Classification Name: Diazo Colorimetry, Bilirubin
FDA Classification: Class II
Review Panel: Clinical Chemistry
Product Code: CIG
Subsequent Product Code: MQM
Regulation Number: 21 CFR 862.1110, 21 CFR 862.1113

4. Predicate Device Information

Predicate Device Name: Roche Cobas C Total Bilirubin Gen. 3
510(k) Number: K131544

5. Intended Use / Indications For Use

The Atellica CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in human serum and plasma of adults and neonates using the Atellica CH Analyzer. Measurement of total bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder block. A total bilirubin measurement in newborn infants is intended to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

Special Conditions for Use Statement: For Prescription Use Only

6. Device Description

Atellica CH Diazo Total Bilirubin is a photometric test using 2,4-dichloroaniline (DCA). Direct bilirubin in presence of diazotized 2,4-dichloroaniline forms a red colored azocompound in acidic solution. A specific mixture of detergents enables the determination of the total bilirubin.

7. Purpose of Submission

The purpose of this submission is a premarket notification for the addition of a neonatal population claim for the Atellica CH Diazo Total Bilirubin (D_TBil) assay.

8. Comparison of Candidate Device and Predicate Device

The tables below describe the similarities and differences between the Atellica CH Diazo Total Bilirubin assay (Candidate Device), and the Roche Cobas C Bilirubin Total Gen 3 assay (Predicate Device).

Substantial equivalence was demonstrated by testing several performance characteristics including reference interval and method comparison.

510(k) Summary of Safety and Effectiveness

Feature	Predicate Device	Candidate Device
	K131544	K251998
	Roche Cobas C Total Bilirubin Gen 3	Atellica CH Diazo Total Bilirubin (D_TBil)
Intended Use	Cobas C Bilirubin Total Gen.3 is an in vitro test for the quantitative determination of total bilirubin in serum and plasma of adults and neonates on Roche/Hitachi Cobas c systems. Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.	The Atellica CH Diazo Total Bilirubin (D_TBil) assay is for in vitro diagnostic use in the quantitative determination of total bilirubin in human serum and plasma of adults and neonates using the Atellica CH Analyzer. Measurement of total bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gallbladder block. A total bilirubin measurement in newborn infants is intended to aid in indicating the risk of bilirubin encephalopathy (kernicterus).
Sample Type	(Adult & Neonate) Human serum and plasma (lithium heparin, dipotassium EDTA)	(Adult & Neonate) Human serum and plasma (lithium heparin, sodium heparin, dipotassium EDTA)
Units of Measure	mg/dL	mg/dL
Assay Range / Measuring Interval	0.146-35.1 mg/dL	0.10 mg/dL – 25.00 mg/dL
Expected Values	Adults: up to 1.2 mg/dL Children with age ≥ 1 month: up to 1.0 mg/dL Newborns: Term and near-term Age of Newborn:	Children >5 days- Adults: 0.3mg/dL – 1.2 mg/dL Neonate: 0-1 Day < 8.00mg/dL

510(k) Summary of Safety and Effectiveness

Feature	Predicate Device	Candidate Device
	K131544	K251998
	Roche Cobas C Total Bilirubin Gen 3	Atellica CH Diazo Total Bilirubin (D_TBil)
	24 hours ≥ 8.0 mg/dL 48 hours ≥ 13.0 mg/dL 84 hours ≥ 17.0 mg/dL	1-2 Days <12.00 mg/dL 3-5 Days <16.00 mg/dL
Assay Principle	Cobas c Bilirubin Total Gen.3 measures total bilirubin by employing the diazo colorimetric method. Total bilirubin, in the presence of a suitable solubilizing agent, is coupled with a diazonium ion in a strongly acidic medium. The color intensity of the red azo dye formed is directly proportional to the total bilirubin and can be determined photometrically.	Photometric test using 2,4-dichloroaniline (DCA). Direct bilirubin in presence of diazotized 2,4- dichloroaniline forms a red colored azocompound in acidic solution. A specific mixture of detergents enables the determination of the total bilirubin.
Standardization	Standardized against the Doumas manual reference method	NIST Standard Reference Material 916
Detection Limits	LoB: 0.10 mg/dL LoD: 0.15 mg/dL LoQ: 0.15 mg/dL	LoB: 0.01mg/dL LoD: 0.02mg/dL LoQ: 0.10mg/dL
Composition	R1: Detergent, Buffer, and Stabilizers at 1.0pH R2: 3,5 Dichlorophenyl diazonium salt ≥1.35mmol/L	**Pack 1:** **Well 1 Reagent 1:** 23.5mL Phosphate buffer (50mmol/L) ; NaCl (150mmol/L) **Well 2 Reagent 1:** 23.5mL Phosphate buffer (50mmol/L) ; NaCl (150mmol/L) **Pack 2:** **Well 1 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (130 mmol/L); Na-Nitrite

Feature	Predicate Device	Candidate Device
	K131544	K251998
	Roche Cobas C Total Bilirubin Gen 3	Atellica CH Diazo Total Bilirubin (D_TBil)
		(0.5 mmol/L) **Well 2 Reagent 2:** 8.8mL 2,4-Dichloroaniline (5 mmol/L); HCl (130 mmol/L); Na-Nitrite (0.5 mmol/L)

9. Standard/Guidance Document References

The following recognized standards from Clinical Laboratory Standards Institute (CLSI) were used as a basis of the study procedures described in this submission:

- Interference Testing in Clinical Chemistry (CLSI EP07).
- Measurement Procedure Comparison and Bias Estimation Using Patient Samples (CLSI EP09-A3).
- Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition (CLSI EP28-A3c).

10. Performance Characteristics for Atellica CH Diazo Total Bilirubin (D_TBil)

10.1 Method Comparison

Specimen Type	Comparison Assay (x)	Regression Equation (µmol/L)	Sample Range mg/dL (µmol/L)	N	r
Serum	Roche Cobas C Total Bilirubin Gen 3	y = 1.06x - 0.02mg/dL (y = 1.06x - 0.34 µmol/L)	0.10 - 21.81 (1.71 - 372.95)	124	0.997

10.2 Reference Interval

Age (days)	Fluid Type	Reference Interval common unit (SI)
0-1	Serum	< 8.00 mg/dL (< 136.80 µmol/L)
1-2	Serum	< 12.00 mg/dL (< 205.20 µmol/L)
3-5	Serum	< 16.00 mg/dL (< 273.60 µmol/L)

10.3 HbF Interference

Interferent	Interferent Concentration (SI)	Control Pool Observed Analyte (SI)	% Bias from Control
Fetal Hemoglobin (HbF)	1000 mg/dL (10.0 g/L)	1.06 mg/dL (18.13 µmol/L)	-4.7
Fetal Hemoglobin (HbF)	1000 mg/dL (10.0 g/L)	13.92 mg/dL (238.03 µmol/L)	-6.2

11. Clinical Study

Not applicable.

12. Standardization

The assay is traceable to the NIST Standard Reference Material 916.

13. Clinical Cut-off

Not applicable

14. Conclusion

The results from the performance studies support that the Candidate Device, Atellica CH Diazo Total Bilirubin (D_TBil) assay is substantially equivalent to the Predicate Device, Roche Cobas C Total Bilirubin Gen. 3(K131544)