May 16, 2025

SENTINEL CH. S.p.A.
Patricia Dupé
Head of Quality System
Via Robert Koch, 2
Milan (MI), 20152, Italy

Re: K242585
Trade/Device Name: Cystatin C
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: NDY
Dated: April 10, 2025
Received: April 10, 2025

Dear Patricia Dupé

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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)*
K242585

Device Name
Cystatin C

Indications for Use *(Describe)*
The Cystatin C assay is an in vitro diagnostic test used in the quantitative immunoturbidimetric determination of cystatin C in human serum and plasma on the Alinity c system.
Measurement of cystatin C aids in the diagnosis and treatment of renal diseases.
For laboratory professional use only.

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.

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Administrative Documentation – 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. 510(k) Number

K242585

II. Applicant Name

SENTINEL CH. S.p.A.
Via Robert Koch, 2
Milano (MI)
20152, Italy
+39 02 345 514 1

Primary contact person for all communications:

Patricia Dupé
Head of Quality System
Phone: +39 02 34 551 496
Fax: +39 02 34 551 464
Email: patriciadupe@sentinel.it

Secondary contact person for all communications:

Alessia Moiana
Sr. Regulatory Affairs Specialist
Phone: +39 02 34 551 494
Email: alessiamoiana@sentinel.it

Date Summary Prepared: May 15, 2025

III. Device Name and Classification

Trade name: Cystatin C
Device Classification: Class II
Regulation Description: Creatinine test system
Regulation Number: 862.1225
Product Code: NDY

IV. Predicate Device

Tina-quant Cystatin C Gen.2 (K161817)

V. Description of Device

A. Principles of the Procedure

The Cystatin C assay is an automated clinical chemistry assay.

Cystatin C is a particle-enhanced turbidimetric immunoassay (PETIA) developed to accurately and reproducibly measure cystatin C levels in serum and plasma. Latex particles coated with anti-human cystatin C antibody agglutinate when mixed with sample containing human cystatin C. The change in absorbance due to agglutination of the reaction mixture is proportional to the quantity of human cystatin C in the sample.

Assay standardization

The Cystatin C assay on Alinity c system is aligned to the certified reference material ERM-DA471/IFCC.

The Cystatin C Calibrators are manufactured gravimetrically and are referenced to European Reference Material ERM-DA471/IFCC at each concentration level.

B. Reagent

The various configurations of the Cystatin C for Alinity c Reagent Kit are described below.

	List Number	
	06T3220	**06T3230**
Tests per cartridge	100	250
Number of cartridges per kit	2	2
Tests per kit	200	500
Reagent (R1)	20.8 mL	46.5 mL
Reagent (R2)	7.5 mL	13.7 mL

Volumes (mL) listed in the table above indicate the volume per cartridge.

Each Cystatin C cartridge contains 2 ready to use liquid reagents (R1 and R2).

Active Ingredients	Concentration
Reagent 2: latex particles coated with rabbit IgG against human cystatin C	0.09%

Inactive ingredients:
Reagent 1: buffer and stabilizers. Preservative: sodium azide (< 0.1%)
Reagent 2: buffer and stabilizers. Preservative: sodium azide (< 0.1%)

VI. Indications for Use/Intended Use of the Device

The Cystatin C assay is an *in vitro* diagnostic test used in the quantitative immunoturbidimetric determination of cystatin C in human serum and plasma on the Alinity c system.

Measurement of cystatin C aids in the diagnosis and treatment of renal diseases.

For laboratory professional use only.

VII. Comparison of Technological Characteristics

The similarities and differences between the subject device (Cystatin C, 06T32) and the predicate device (Roche Tina-quant Cystatin C Gen.2) are presented in the table below.

	Subject Device: Cystatin C	**Predicate Device: Roche Tina-quant Cystatin C Gen.2**
General Device Characteristic Similarities		
Intended Use/Indications for Use	The Cystatin C assay is an *in vitro* diagnostic test used in the quantitative immunoturbidimetric determination of cystatin C in human serum and plasma on the Alinity c system. Measurement of cystatin C aids in the diagnosis and treatment of renal diseases. For laboratory professional use only.	In vitro test for the quantitative determination of cystatin C in human serum and plasma on Roche/Hitachi cobas c systems. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.
Methodology	Immunoturbidimetric	Same
Principal of Operation	Particle-enhanced turbidimetric immunoassay	Same
Specimen Type	Human serum and plasma	Same

	Subject Device: **Cystatin C**	**Predicate Device:** **Roche Tina-quant Cystatin C Gen.2**
Measurement Type	Quantitative	Same
Tube Type	Serum, Li-heparin, Na-heparin, K2-, and K3- EDTA plasma	Serum, Li-heparin, K2-, and K3-EDTA plasma
Standardization	This method has been standardized against ERM-DA471/IFCC.	Same
General Device Differences		
Measuring Interval	Analytical Measuring Interval (AMI): 0.30–10.00 mg/L Extended Measuring Interval (EMI): 10.00–40.00 mg/L Reportable Range (RI): 0.30–40.00 mg/L	Measuring Range: 0.40–6.80 mg/L Extended Measuring Range: 6.80–10.20 mg/L
Hook Effect	No prozone effect was observed up to 40.00 mg/L.	No false result occurs up to a cystatin C concentration of 12 mg/L.
Lower Limits of Measurement	Limit of Blank: 0.03 mg/L Limit of Detection: 0.05 mg/L Limit of Quantitation: 0.30 mg/L	Limit of Blank: 0.30 mg/L Limit of Detection: 0.40 mg/L Limit of Quantitation: 0.40 mg/L
Platform	Alinity c system	Roche/Hitachi cobas c 501

VIII. Summary of Nonclinical Performance

A. Reportable Interval

Based on representative data for the limit of quantitation (LoQ), the ranges over which results can be reported are provided below in accordance with Clinical and Laboratory Standards Institute (CLSI) EP34, 1st ed.*

	mg/L
Analytical Measuring Interval (AMI)[a]	0.30–10.00
Extended Measuring Interval (EMI)[b]	10.00–40.00
Reportable Interval[c]	0.30–40.00

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in mg/L that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] EMI: The EMI extends from the ULoQ to the ULoQ × sample dilution.

[c] The reportable interval extends from the LoQ to the upper limit of the EMI.

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Guideline EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision (20-Day)

A study was performed based on guidance from the CLSI document EP05-A3.* Testing was conducted using 1 lot of Cystatin C reagents, 1 lot of Cystatin C Calibrators, 1 lot of Cystatin C Controls, and 1 instrument. Two controls and 4 human serum panels were tested in a minimum of 2 replicates, twice per day on 20 days.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**n**	**Mean (mg/L)**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	80	0.81	0.01	1.0	0.01	1.7
Control Level 2	80	4.11	0.03	0.6	0.04	1.0
Panel A (native)	80	0.49	0.01	1.7	0.01	1.8
Panel B (native)	80	0.92	0.01	0.8	0.01	0.9
Panel C (native)	80	5.89	0.03	0.5	0.03	0.6
Panel D (supplemented)	80	8.95	0.07	0.8	0.09	1.0

[a] Within-Laboratory variability contains within-run, between-run, and between-day variance components.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI;2014.

C. Reproducibility

A study was performed based on guidance from the CLSI document EP05--A3.* Testing was conducted at each of 3 testing sites using 2 lots of the Cystatin C reagents, 1 lot of the Cystatin C Calibrators, 1 lot of the Cystatin C Controls, and 1 instrument. Two controls and 3 human serum panels were tested in a minimum of 4 replicates at 2 separate times per day on 5 different days.

			Repeatability		Within-Laboratory[a]		Between-Site		Between-Lot		Overall Reproducibility[b]	
Sample	**n**	**Mean (mg/L)**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Control Level 1	240	0.81	0.01	1.5	0.02	2.0	0.00	0.3	0.00	0.0	0.02	2.0
Control Level 2	240	4.08	0.02	0.6	0.04	0.9	0.02	0.5	0.02	0.4	0.04	1.1
Panel 1	240	0.49	0.02	5.0	0.03	5.4	0.00	0.3	0.00	0.0	0.03	5.4
Panel 2	240	0.93	0.01	1.3	0.01	1.6	0.00	0.0	0.00	0.5	0.02	1.6
Panel 3	240	8.80	0.09	1.0	0.13	1.5	0.00	0.0	0.06	0.6	0.14	1.6

[a] Includes repeatability (within-run), between-run, and between-day variability.
[b] Includes repeatability (within-run), between-run, between-day, between-site, and between-lot variability.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures: Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI;2014.

D. Accuracy

A study was performed to estimate the bias of the Cystatin C assay relative to standard reference material (ERM-DA471/IFCC). Testing was conducted using 2 lots of the Cystatin C reagents, 2 lots of the Cystatin C calibrators, and 1 instrument. The bias ranged from 1.3% to 1.8% across all reagent and calibrator lots.

E. Linearity

A study was performed based on guidance from the CLSI document EP06, 2nd ed.[*] This assay is linear across the AMI of 0.30 to 10.00 mg/L.

F. Lower Limits of Measurement

A study was performed based on guidance from the CLSI document EP17-A2.[†] Testing was conducted using 3 lots of the Cystatin C reagents on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	mg/L
LoB[a]	0.03
LoD[b]	0.05
LoQ[c]	0.30

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a total allowable error of 25% was met and was determined from n ≥ 60 replicates of low-analyte level samples.

[*] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures.* 2nd ed. CLSI Guideline EP06. Wayne, PA: CLSI; 2020.

[†] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition.* CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

G. Analytical Specificity

1. Potentially Interfering Endogenous Substances

A study was performed based on guidance from the CLSI document EP07, 3rd ed.[*] Each substance was tested at 2 levels of the analyte (approximately 0.79 and 3.95 mg/L).

No significant interference (interference within ± 0.08 mg/L for samples < 0.79 mg/L) was observed at the following concentrations.

Potentially Interfering Substance	Interferent Level
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Hemoglobin	1000 mg/dL
Rheumatoid factor	550 IU/mL
Total protein	10.2 g/dL
Triglycerides	1500 mg/dL

No significant interference (interference within ± 10.0% for samples ≥ 0.79 mg/L) was observed at the following concentrations.

Potentially Interfering Substance	Interferent Level
Bilirubin (conjugated)	60 mg/dL
Bilirubin (unconjugated)	60 mg/dL
Hemoglobin	1000 mg/dL
Rheumatoid factor	1200 IU/mL
Total protein	11.8 g/dL
Triglycerides	1500 mg/dL

[*] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

Interference beyond ± 0.08 mg/L for samples < 0.79 mg/L and beyond ± 10.0% for samples ≥ 0.79 mg/L (based on 95% Confidence Interval [CI]) was observed at the concentrations shown below for the following substances.

Potentially Interfering Substance	Interferent Level	Analyte Level	% Interference (95% CI)
Rheumatoid factor	1200 IU/mL	0.79 mg/L	0.19 (0.16, 0.22)
Total protein	15 g/dL	0.79 mg/L	0.27 (0.26, 0.28)
Total protein	15 g/dL	3.95 mg/L	18.5% (18.0%, 18.9%)

2. Potentially Interfering Exogenous Substances

A study was performed based on guidance from the CLSI document EP07, 3rd ed.[*] Each substance was tested at 2 levels of the analyte (approximately 0.79 and 3.95 mg/L).

No significant interference (interference within ± 0.08 mg/L for samples < 0.79 mg/L and within ± 10.0% for samples ≥ 0.79 mg/L) was observed at the following concentrations.

Potentially Interfering Drug	Interferent Level	Potentially Interfering Drug	Interferent Level
Acetaminophen	250 mg/L	Doxycycline	50 mg/L
Acetylcysteine	150 mg/L	Ibuprofen	500 mg/L
Acetylsalicylic acid	1000 mg/L	Levodopa	20 mg/L
Ampicillin-Na	1000 mg/L	Methyldopa	22.5 mg/L
Ascorbic acid	300 mg/L	Metronidazole	200 mg/L
Biotin	3510 ng/mL	Phenylbutazone	400 mg/L
Ca-dobesilate	200 mg/L	Rifampicin	60 mg/L
Cefoxitin	6600 mg/L	Sodium heparin	10 U/mL
Cyclosporin	5 mg/L	Theophylline (1,3-dimethylxanthine)	100 mg/L

[*] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry.* 3rd ed. CLSI Guideline EP07. Wayne, PA: CLSI; 2018.

H. Method Comparison

A study was performed based on guidance from the CLSI document EP09c, 3rd ed.* using the Passing-Bablok regression method.

Cystatin C on Alinity c vs a Comparator Cystatin C assay

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	161	mg/L	1.00	-0.07	1.03	0.60–8.20

I. Matrix Comparison (Tube Type Equivalence)

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Cystatin C assay. The following blood collection tube types were determined to be acceptable for use with the Cystatin C assay:

Serum

- Serum
- Serum separator

Plasma

- Dipotassium EDTA
- Lithium heparin
- Lithium heparin separator
- Sodium heparin
- Tripotassium EDTA

J. High Dose Hook

There is no prozone interference for undiluted samples containing up to 40.00 mg/L of cystatin C.

* Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples*. 3rd ed. CLSI Guideline EP09c. Wayne, PA: CLSI; 2018.

K. Expected Values (Reference Interval)

A study was performed based on guidance from CLSI EP28-A3c.* Testing was conducted on apparently healthy individuals, including 105 females and 145 males, with an estimated glomerular filtration rate (eGFR) > 80 (mL/min/1.73 m^2). The age of the study population ranged from 18 to 69 years.

The reference range using the 2.5th and 97.5th percentile is summarized below.

	Range (mg/L)
Adult	0.59–1.28

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion

The information presented in this 510(k) premarket notification demonstrate that the performance of the subject device, Cystatin C for use with Alinity c system (List Number 06T32), is substantially equivalent to the predicate device, Tina-quant Cystatin C Gen.2 (K161817).

The minor differences between predicated device and candidate device raise no new issues of safety and effectiveness and do not impact the indications for use or technological characteristics.

* Clinical and Laboratory Standards Institute (CLSI). *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition.* CLSI document EP28-A3c. Wayne, PA: CLSI; 2008.